

The MDIS product journeys, as a browser drove them

A manufacturer registers a device, releases documents, responds to partner review, publishes instructions and records a vigilance event; platform administrators provision an organisation and inspect its audit trail. These executed journeys show the product being used on the disposable stack, with API checks alongside the pictures. They provide evidence for the named run; client suitability and approval remain to be assessed.

RUN

gh-34316989410-1

RECORDED

2026-09-09T06:20:00Z

STACK

deploy/mdis-e2e · seeded personas · storage emulator

TESTED CANDIDATE

4d3a5e7a70c40f31f4bea7e7ec6b481514765e6b

EXECUTION

37 selected scenarios · 407 steps · 407 passed · 0 failed

CAPTURES

272 distinct source captures; auth-secret-safe journeys excluded

Qualification receipt

QUALIFICATION

complete-shared-machine-run

RECEIPT CANDIDATE

4d3a5e7a70c40f31f4bea7e7ec6b481514765e6b

WORKFLOW SOURCE COMMIT

4d3a5e7a70c40f31f4bea7e7ec6b481514765e6b

EVIDENCE ARTIFACT

mdis-e2e-evidence · 10090704756

RECEIPT RUN

gh-34316989410-1

RECORDED

2026-09-09T06:20:00Z

WORKFLOW

[GitHub run](#)

ARTIFACT SHA-256

fc63b5a5515807d189bde9ce96d1a5633ae758f28eb735fab99784644958637b

SOURCE MANIFEST SHA-256

1844547485349d3dac284c2af6e2b9e6b190dc50bfbe876ff4f49b1026b0a65a

VERIFIED FILES

3055

SUITE COUNTS

121 normal + 8 secret-safe passed

Required jobs:

- apiPostgreSQL: **success**
- disposableEndToEnd: **success**
- required: **success**

Register a device

A manufacturer adds a device, opens its first change, files a document, and clears the release check.

features/redesign/manufacturer-adds-a-device.feature · @MODULE:REDESIGN @SR-014

PASS

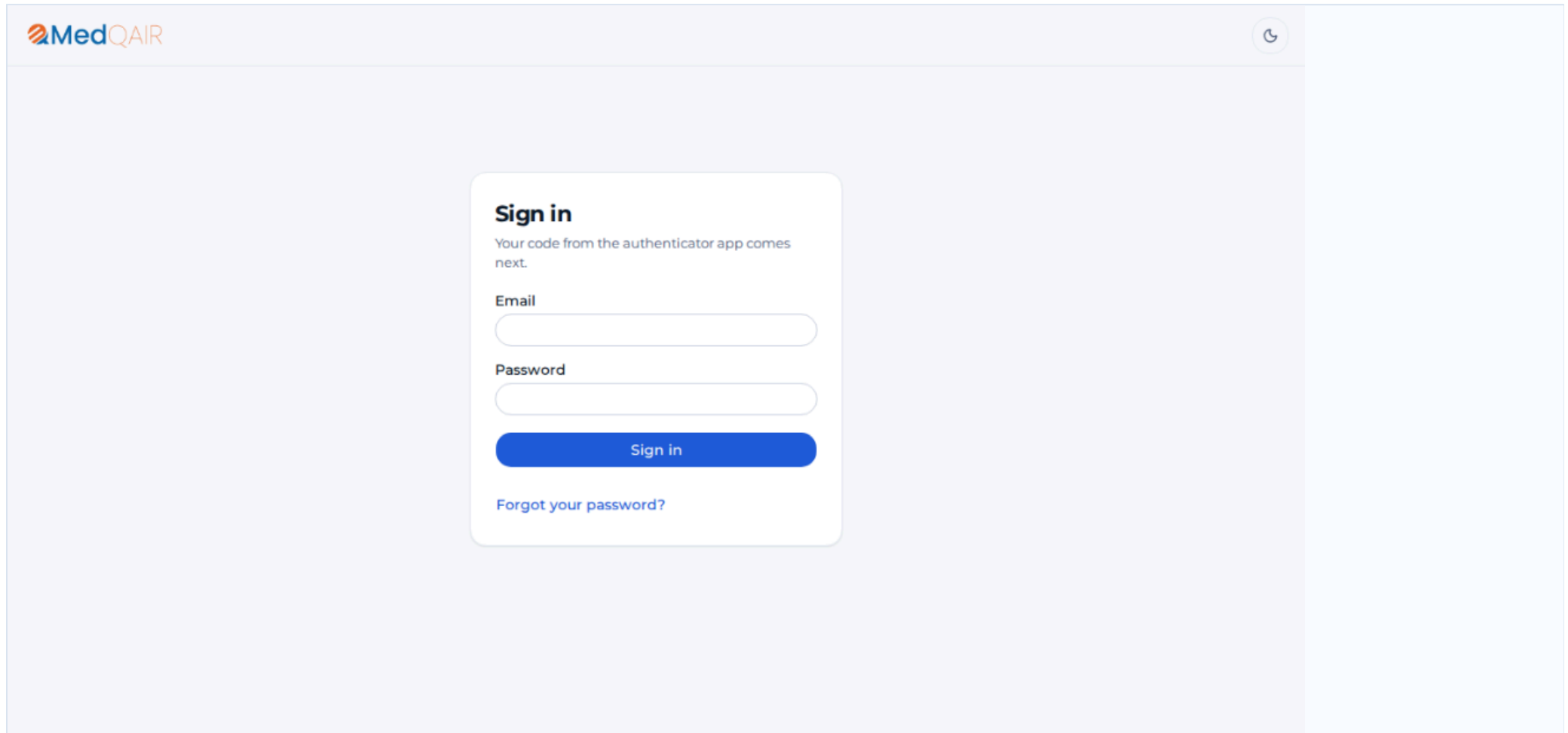
adding a device is offered, and works

01

EXECUTED GHERKIN STEP

Given the redesign sign-in page

PASS



Capture SHA-256: 953d9a1220a1b501a0ede3a87b7d5516c6552f0e0d727f3b59246c01ef255e3b

02

EXECUTED GHERKIN STEP

When I sign in to the redesign as a manufacturer **PASS**

 **Technical file** 

   **[TEST] Northstar Medical Im...** 
Manufacturer 

Your work

[TEST] Northstar Medical Imaging · Wednesday 9 September

 **5**
drafts to finish

 **0**
returned for changes

 **0**
waiting on a partner

 **28**
devices, 5 released

 Add a device

Needs you

5 drafts

 **NL**

Northstar LumaDerm Phototherapy Lamp
Change 1 · first release

Continue

 **NC**

Northstar CardioMesh Coronary Stent
1.0 first release

Continue

 **NS**

Northstar SonoLite Handheld Ultrasound
1.0 first release

Continue

 **NV**

Northstar VitalSync Patient Monitor
1.1 labelling update

Continue

 **E**

E2E Journey Device 1788933641806128
Change 1 · 1.0.0 · first release

Continue

Devices · 28

All 28 >

 **PA**

PulseView AR Validation ...

Unreleased

 **AI**

AtlasView Importer Verifi...

Unreleased

 **AO**

AtlasView Ownership Bo...

Unreleased

 **AD**

AtlasView Distributor Veri...

Unreleased

 **AD**

AtlasView Distributor Gu...

Unreleased

 **AA**

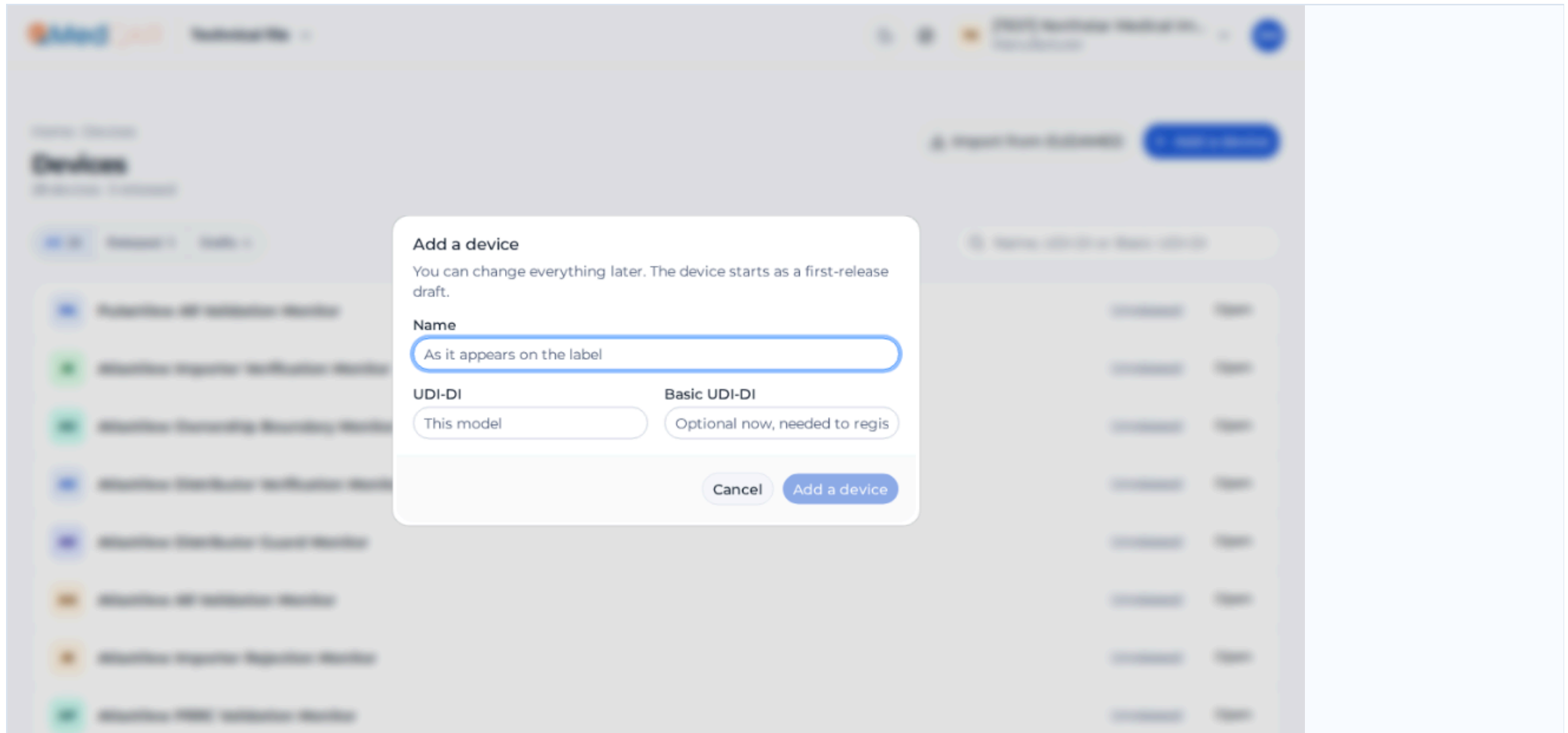
AtlasView AR Validation ...

Unreleased

Capture SHA-256: 46e03938ae0c93c06144b52d38f56180830d5589e23ec00f6462e471ac066695

03

EXECUTED GHERKIN STEP

And I open the redesign's add-device form **PASS**

Capture SHA-256: 9cb1bc7f9fddac3a88103cf94505443137b3e33ab310c1742626509801e4a11c

04

EXECUTED GHERKIN STEP

And I submit a device with a unique name and UDI-DI PASS

 Technical file 

  [TEST] Northstar Medical Im...  

Home > Devices > E2E Journey Device 1788933701620633

 **E2E Journey Device 1788933701620633** Unreleased
not released yet · Basic UDI-DI —

Choose who 

Changes and releases

No changes yet.

Registration Open

Not started. EUDAMED needs every answer.

Who can open it Choose who

Only you, so far.

Identification

UDI-DI
E2E-1788933701620633

Basic UDI-DI
—

UDI-PI
—

Capture SHA-256: 120065ee674df017ef40a357d785b7a0e4ad4ec18df8ba1b70ebcf8c49718424

05

EXECUTED GHERKIN STEP

Then the redesign shows the device it just created **PASS***No visible change at this step; the asserted state was already present*

 **Technical file** 

   [TEST] Northstar Medical Im...  

Home › Devices › E2E Journey Device 1788933701620633

 **E2E Journey Device 1788933701620633** Unreleased
not released yet · Basic UDI-DI —

Choose who 

Changes and releases

No changes yet.

Registration Open

Not started. EUDAMED needs every answer.

Who can open it Choose who

Only you, so far.

Identification

UDI-DI
E2E-1788933701620633

Basic UDI-DI
—

UDI-PI
—

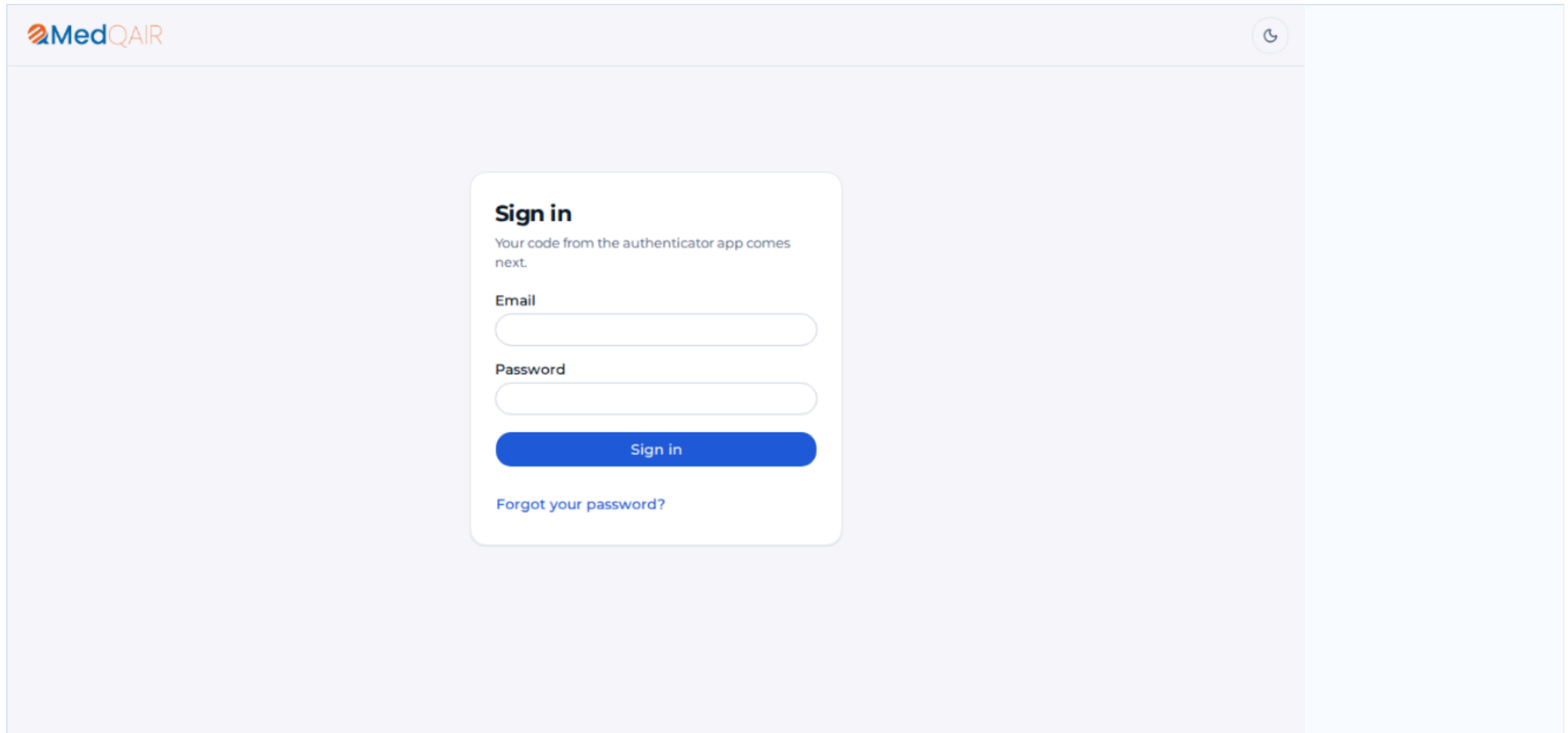
Capture SHA-256: 120065ee674df017ef40a357d785b7a0e4ad4ec18df8ba1b70ebcf8c49718424

the first release opens a change on a brand-new device

01

EXECUTED GHERKIN STEP

Given the redesign sign-in page **PASS**



Capture SHA-256: 953d9a1220a1b501a0ede3a87b7d5516c6552f0e0d727f3b59246c01ef255e3b

02

EXECUTED GHERKIN STEP

When I sign in to the redesign as a manufacturer **PASS**

 Technical file 

   [TEST] Northstar Medical Im...  

Your work

[TEST] Northstar Medical Imaging - Wednesday 9 September

 **5**
drafts to finish

 **0**
returned for changes

 **0**
waiting on a partner

 **29**
devices, 5 released

 Add a device

Needs you

5 drafts

	Northstar CardioMesh Coronary Stent 1.0 first release	
	Northstar LumaDerm Phototherapy Lamp Change 1 - first release	
	Northstar SonoLite Handheld Ultrasound 1.0 first release	
	Northstar VitalSync Patient Monitor 1.1 labelling update	
	E2E Journey Device 1788933641806128 Change 1 - 1.0.0 - first release	

Devices - 29

All 29 >

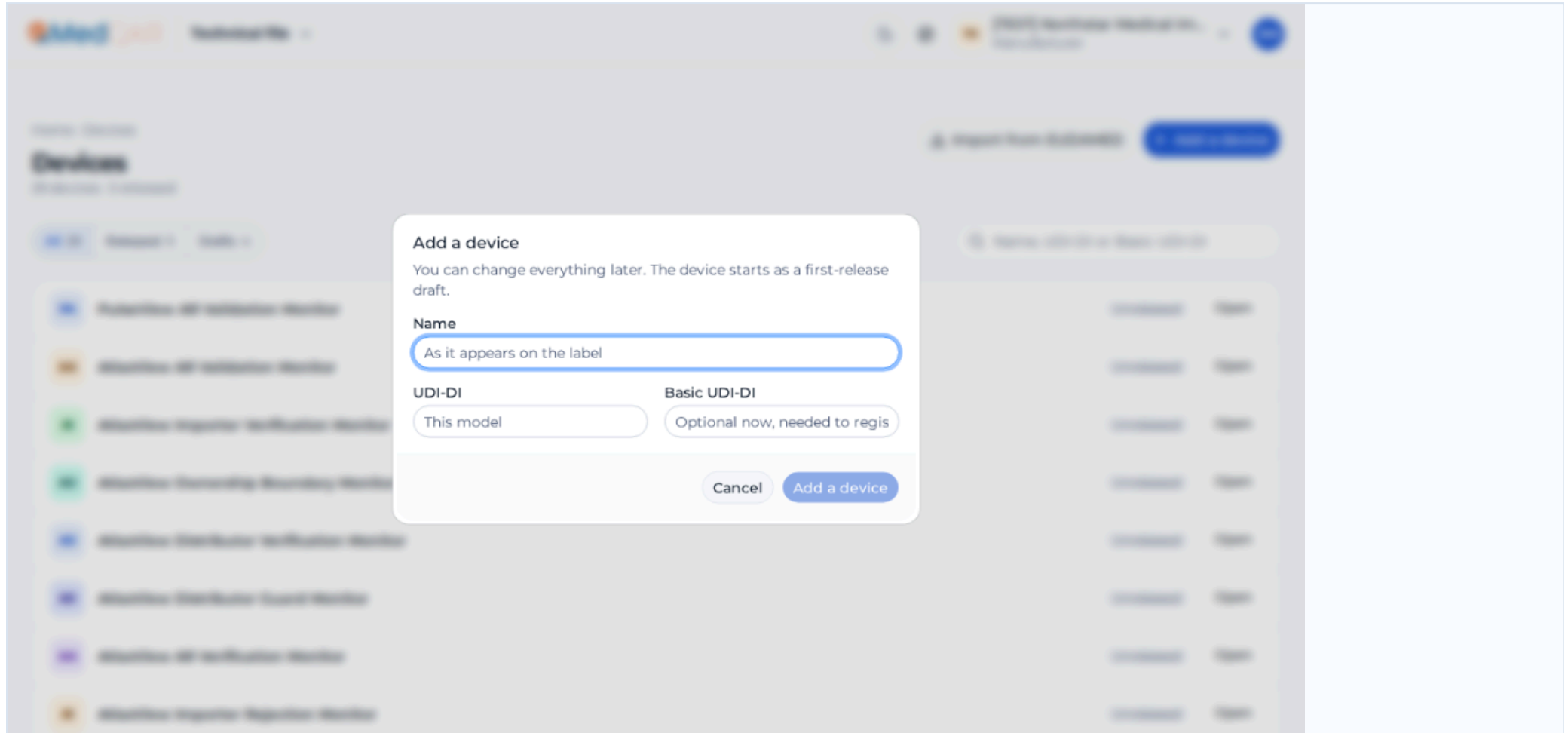
 Name, UDI-DI or Basic UDI-DI

	PulseView AR Validation ...	
	AtlasView AR Validation ...	
	AtlasView Importer Verifi...	
	AtlasView Ownership Bo...	
	AtlasView Distributor Veri...	
	AtlasView Distributor Gu...	

Capture SHA-256: 199b275e18c66c048dc6a71b040292fb9bccaa6abd8e0d889252f1773ebceefe

03

EXECUTED GHERKIN STEP

And I open the redesign's add-device form **PASS**

Capture SHA-256: be4da505072b2c60cad69504122cc2d61411d8bd3498e747ed87961ec014b06c

04

EXECUTED GHERKIN STEP

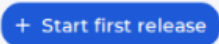
And I submit a device with a unique name and UDI-DI PASS

 Technical file 

  [TEST] Northstar Medical Im...  

Home > Devices > E2E Journey Device 1788933703671839

 **E2E Journey Device 1788933703671839** Unreleased
not released yet · Basic UDI-DI —

Choose who 

Changes and releases

No changes yet.

Registration Open

Not started. EUDAMED needs every answer.

Who can open it Choose who

Only you, so far.

Identification

UDI-DI
E2E-1788933703671839

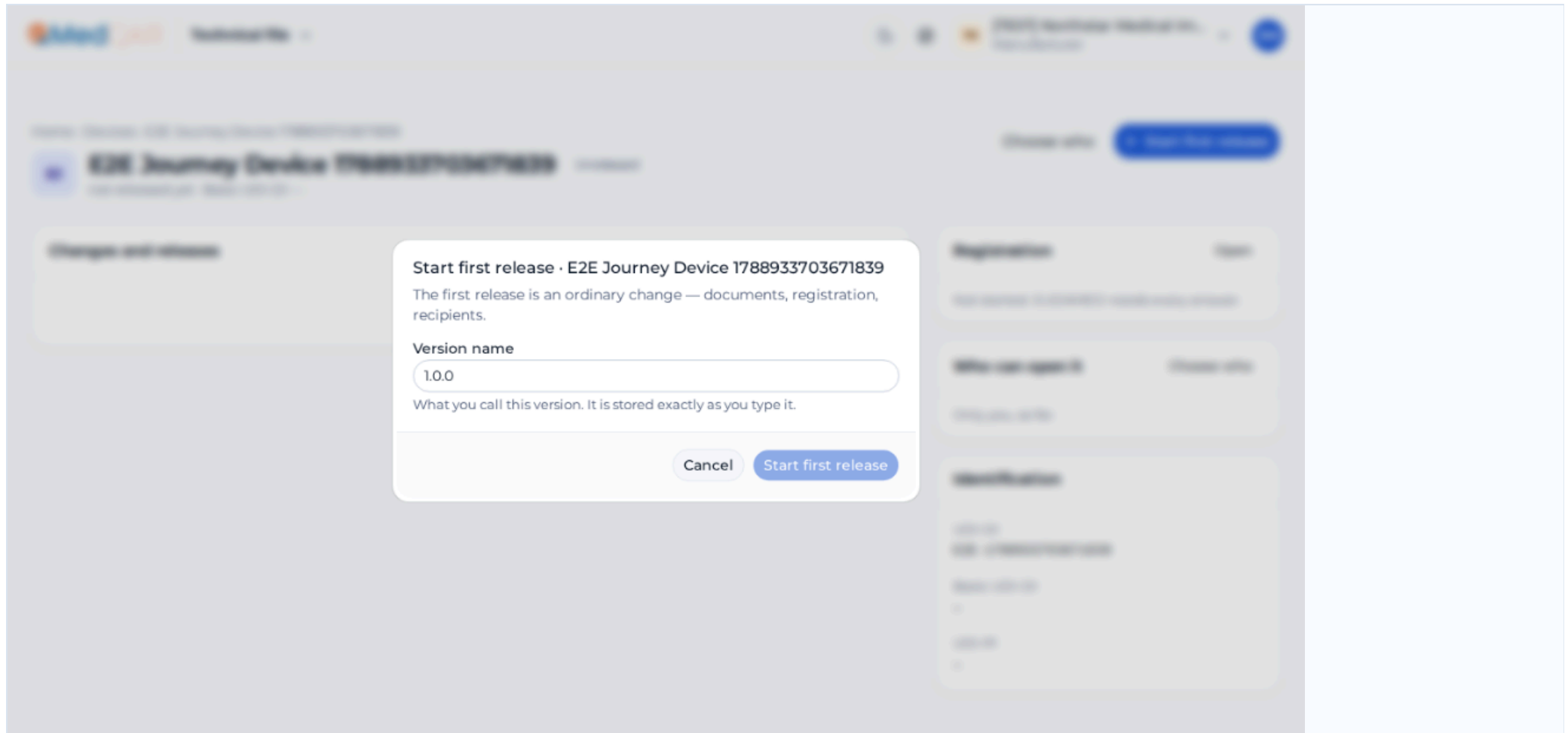
Basic UDI-DI
—

UDI-PI
—

Capture SHA-256: b441becbd85d5956ed7173a0660be2886d055480d349493469e1eb20db34fccc

05

EXECUTED GHERKIN STEP

And I start the device's first release PASS

Capture SHA-256: 90963878fe9046c5494cd169f7845697c649947e7636f0363cf6796a94fc7b7e

06

EXECUTED GHERKIN STEP

Then the redesign opens a draft change for it PASS

MedQAIR Technical file

Home › E2E Journey Device 1788933703671839 › Change 1

Change 1 Draft
Version 1.0.0 Rename

Discard draft Release

Documents 0 Find Add files

Drop PDFs here · section guessed from the filename, you confirm

No documents yet.

Ready to release? Ready

- ✓ Every upload has a section.
Settings / Review policy · Documents
- ⚠ This device's target market is not recorded — add its EUDAMED registration from the device's Registration page; the registration records the market.
Who receives it · Release authority & reviewers · recommended — you can still release
MDIS compares your organisation's country (from its SRN) with this device's market. Your representative is appointed under Who receives it — a partner you are already connected to at once, a new one once they accept the invitation.
Confirming records that the appointment covers this market.
[Open Who receives it](#)

Capture SHA-256: ce70ecffac345d2fcf0dd4ef442e070f29e9414b73ae6fad345b48968e05dc8f

07

EXECUTED GHERKIN STEP

And the change says registration has not started rather than failed PASS

No visible change at this step; the draft change already shows the asserted registration state

 **Technical file** 

 **TN** [TEST] Northstar Medical Im...  **EM**

Home › E2E Journey Device 1788933703671839 › Change 1

 **Change 1** Draft
Version 1.0.0 [Rename](#)

 **Documents** 0 [Add files](#)

 **Drop PDFs here** · section guessed from the filename, you confirm

No documents yet.

Ready to release? Ready

 **Every upload has a section.**
Settings / Review policy · Documents

 **This device's target market is not recorded — add its EUDAMED registration from the device's Registration page; the registration records the market.**
Who receives it · Release authority & reviewers · recommended — you can still release
MDIS compares your organisation's country (from its SRN) with this device's market. Your representative is appointed under Who receives it — a partner you are already connected to at once, a new one once they accept the invitation. Confirming records that the appointment covers this market.
[Open Who receives it](#)

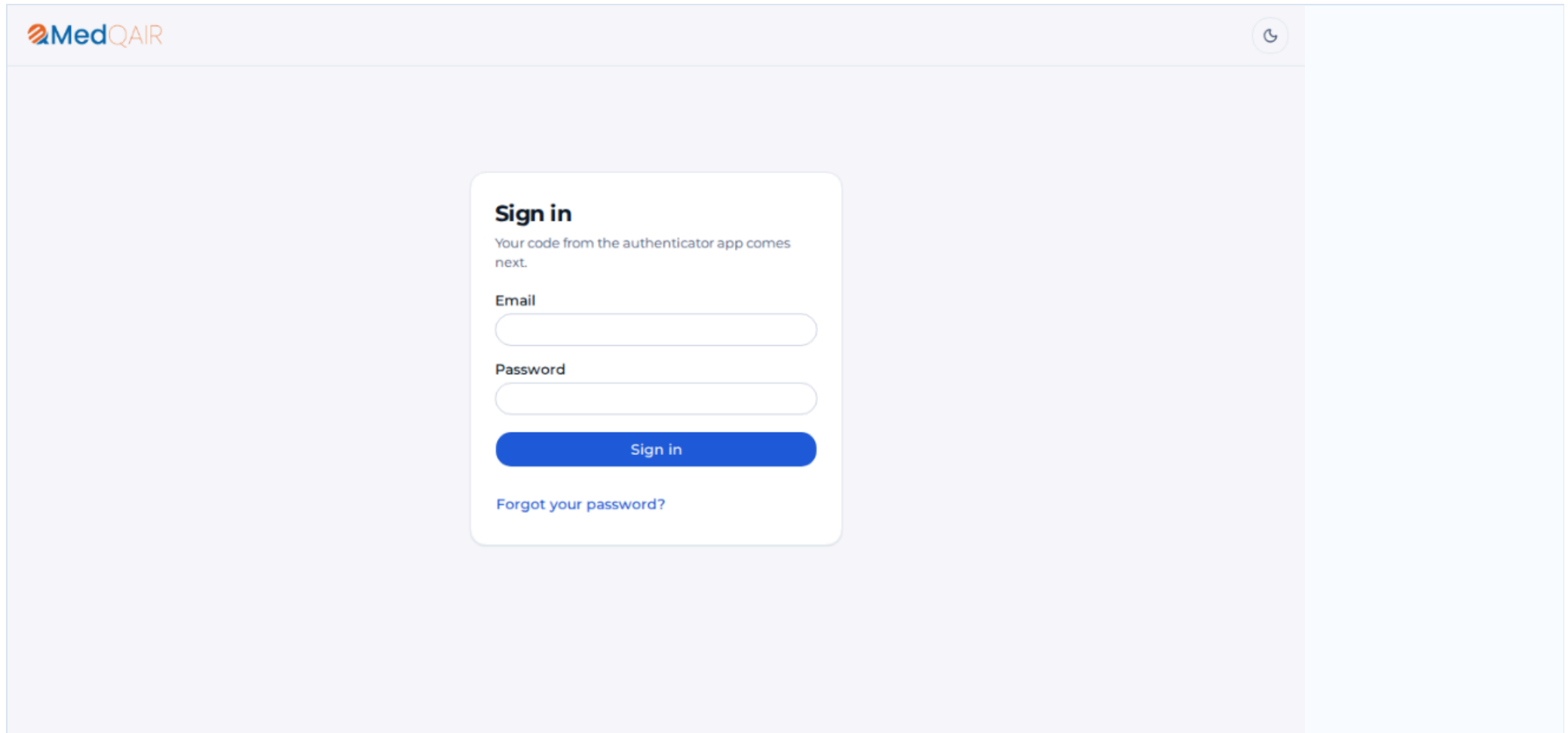
Capture SHA-256: ce70ecffac345d2fcf0dd4ef442e070f29e9414b73ae6fad345b48968e05dc8f

a document is uploaded into the first release

01

EXECUTED GHERKIN STEP

Given the redesign sign-in page **PASS**



Capture SHA-256: 953d9a1220a1b501a0ede3a87b7d5516c6552f0e0d727f3b59246c01ef255e3b

02

EXECUTED GHERKIN STEP

When I sign in to the redesign as a manufacturer **PASS**

 Technical file 

   [TEST] Northstar Medical Im...  
Manufacturer

Your work

[TEST] Northstar Medical Imaging · Wednesday 9 September

 **6**
drafts to finish

 **0**
returned for changes

 **0**
waiting on a partner

 **30**
devices, 5 released

 Add a device

Needs you

6 drafts

 **NC**

Northstar CardioMesh Coronary Stent
1.0 first release

Continue

 **NL**

Northstar LumaDerm Phototherapy Lamp
Change 1 · first release

Continue

 **NS**

Northstar SonoLite Handheld Ultrasound
1.0 first release

Continue

 **NV**

Northstar VitalSync Patient Monitor
1.1 labelling update

Continue

 **E**

E2E Journey Device 1788933641806128
Change 1 · 1.0.0 · first release

Continue

 **E**

E2E Journey Device 1788933703671839
Change 1 · 1.0.0 · first release

Continue

Devices · 30

All 30 >

 **PA**

PulseView AR Validation ...

Unreleased

 **AA**

AtlasView AR Verification ...

Unreleased

 **AA**

AtlasView AR Validation ...

Unreleased

 **AI**

AtlasView Importer Verifi...

Unreleased

 **AD**

AtlasView Distributor Veri...

Unreleased

 **AD**

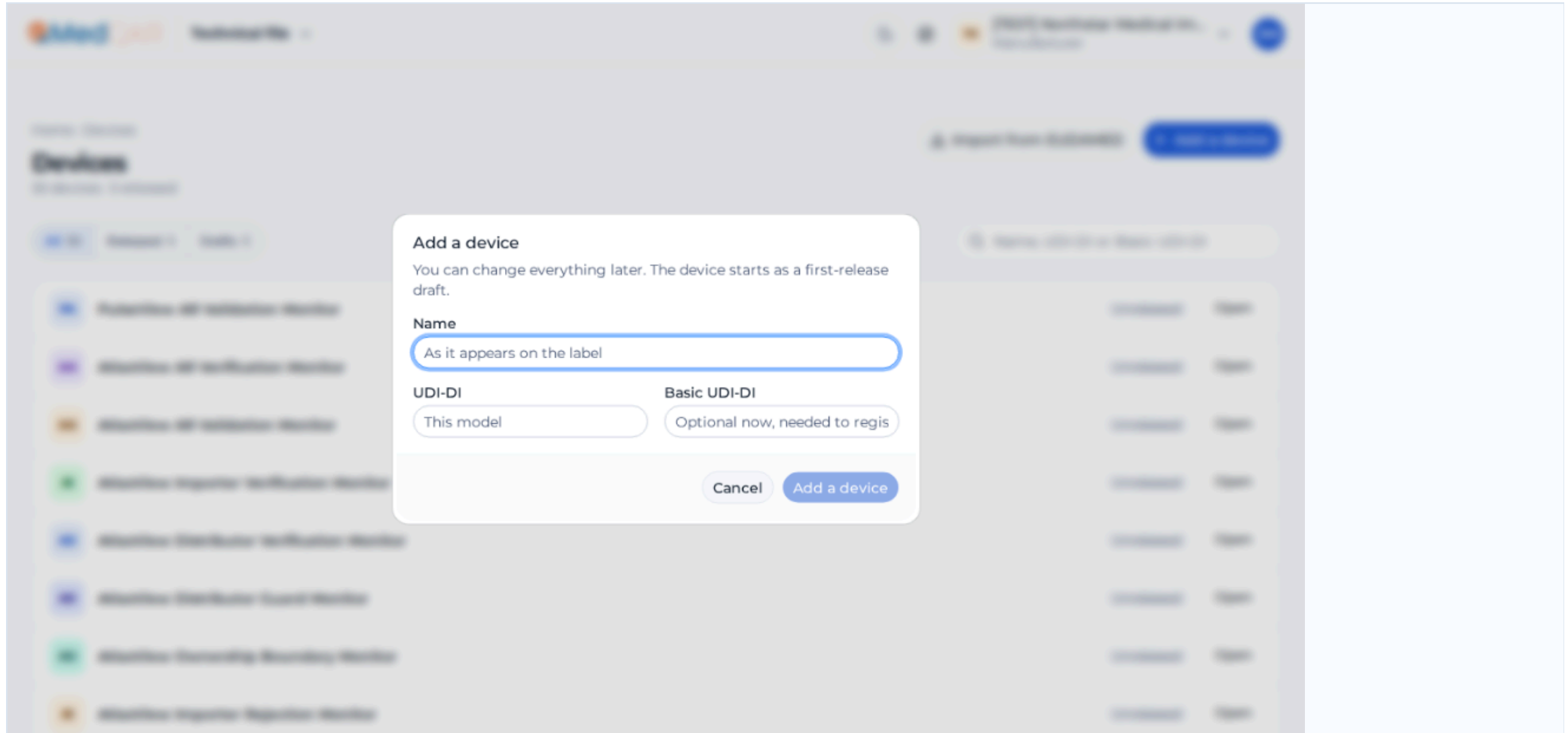
AtlasView Distributor Gu...

Unreleased

Capture SHA-256: 8d3e36cd3b40be6a76e082f453ef6d8423b8aa94f4bfd13031bc51dc78e6a8ea

03

EXECUTED GHERKIN STEP

And I open the redesign's add-device form **PASS**

Capture SHA-256: 4f6ab3e808b10f48dbfd391ce21df3c753dcda21a35f9e1b5a51633d3bbbc11c

04

EXECUTED GHERKIN STEP

And I submit a device with a unique name and UDI-DI PASS

 Technical file 

 TN [TEST] Northstar Medical Im...  EM

Home > Devices > E2E Journey Device 1788933706274996

 **E2E Journey Device 1788933706274996** Unreleased
not released yet · Basic UDI-DI —

Choose who [+ Start first release](#)

Changes and releases

No changes yet.

Registration Open

Not started. EUDAMED needs every answer.

Who can open it Choose who

Only you, so far.

Identification

UDI-DI
E2E-1788933706274996

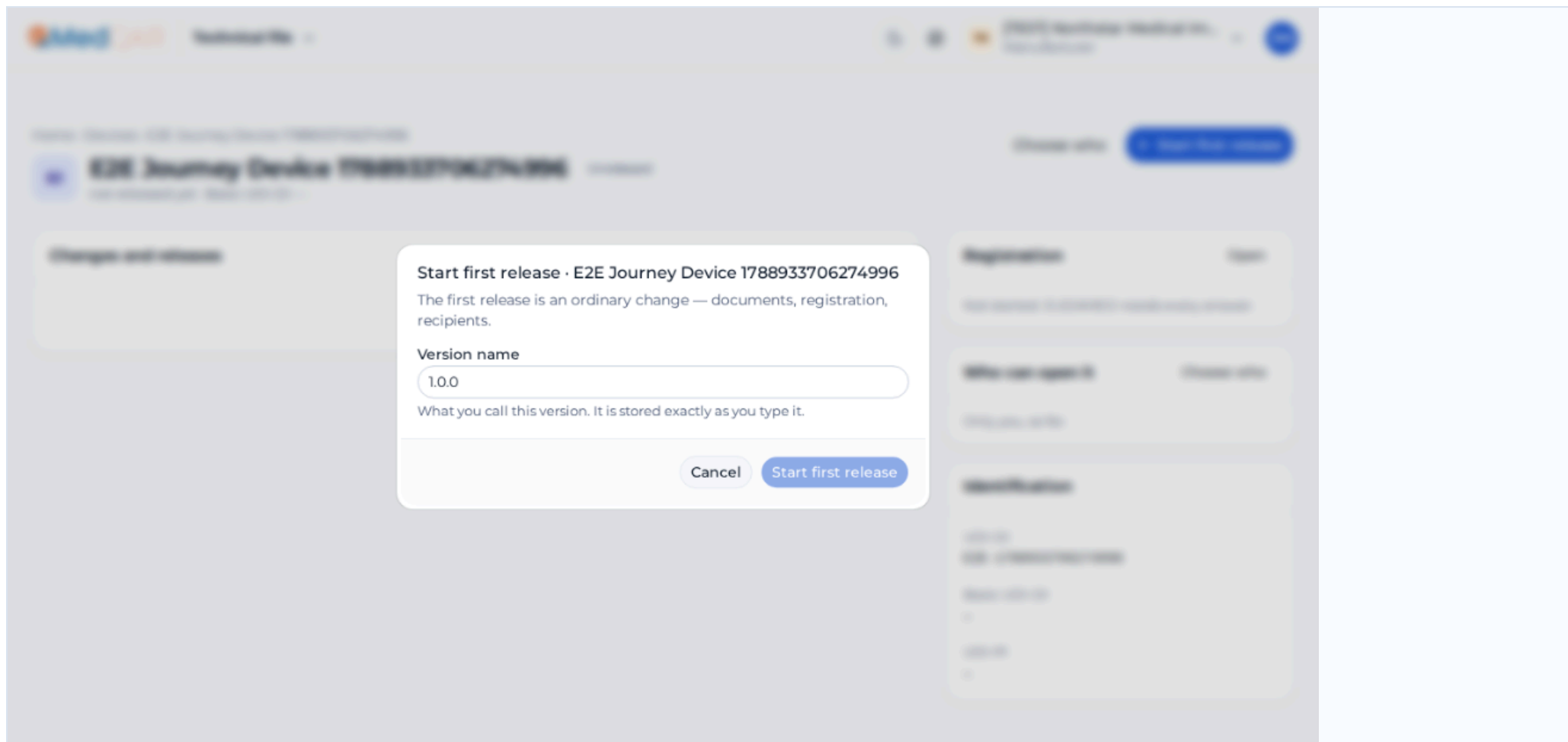
Basic UDI-DI
—

UDI-PI
—

Capture SHA-256: 6aca2c4b5a5ed04eaec47a7825ae319105ae4911a701453bb938150286eac351

05

EXECUTED GHERKIN STEP

And I start the device's first release PASS

Capture SHA-256: 8b27a786f000e0dc1ac2ca4ab3a7a3ede8ead34a55d96d28daacf9405bc89716

06

EXECUTED GHERKIN STEP

And I upload a document to the change PASS

 Technical file ▼

↻ TN [TEST] Northstar Medical Im... ▼ EM
Manufacturer

Home › E2E Journey Device 1788933706274996 › Change 1

Discard draft Release

 **Change 1** Draft

Version 1.0.0 Rename

 **Documents** 1 · 1 changed

 Add files

 Drop PDFs here · section guessed from the filename, you confirm

 IFU & labelling

1 document

☐ multi-eo-product-label.pdf

New

 ...

Ready to release? Ready

 **Every upload has a section.**
Settings / Review policy · Documents

 **This device's target market is not recorded — add its EUDAMED registration from the device's Registration page; the registration records the market.**
Who receives it · Release authority & reviewers · recommended — you can still release
MDIS compares your organisation's country (from its SRN) with this device's market. Your representative is appointed under Who receives it — a partner you are already connected to at once, a new one once they accept the invitation. Confirming records that the appointment covers this market.
[Open Who receives it](#)

Capture SHA-256: a7af0569c1b625bf06b410bfea9a9a3447fdc135acb6b225fe22bc0944c3447c

07

EXECUTED GHERKIN STEP

Then the change lists the uploaded document PASS

No visible change at this step; the asserted state was already present

MedQAIR Technical file

Home › E2E Journey Device 1788933706274996 › Change 1

Change 1 Draft
Version 1.0.0 Rename

Documents 1 · 1 changed Find Add files

Drop PDFs here · section guessed from the filename, you confirm

IFU & labelling 1 document

☐	multi-eo-product-label.pdf New	Ⓜ ...
--------------------------	-----------------------------------	-------

Ready to release? Ready

- ✓ Every upload has a section.
Settings / Review policy · Documents
- ⚠ This device's target market is not recorded — add its EUDAMED registration from the device's Registration page; the registration records the market.
Who receives it · Release authority & reviewers · recommended — you can still release
MDIS compares your organisation's country (from its SRN) with this device's market. Your representative is appointed under Who receives it — a partner you are already connected to at once, a new one once they accept the invitation. Confirming records that the appointment covers this market.
[Open Who receives it](#)

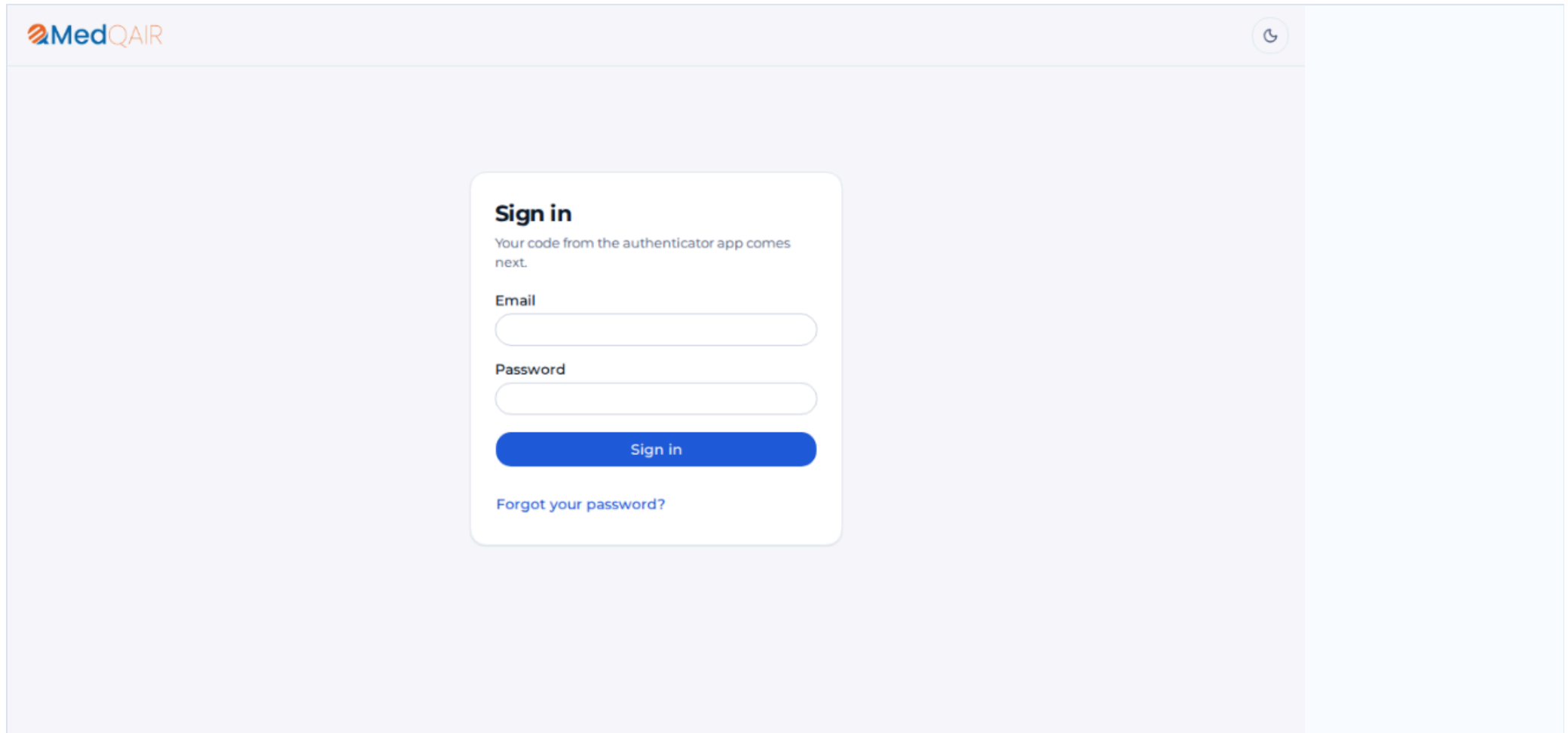
Capture SHA-256: a7af0569c1b625bf06b410bfea9a9a3447fdc135acb6b225fe22bc0944c3447c

the document is filed, and the release check clears

01

EXECUTED GHERKIN STEP

Given the redesign sign-in page **PASS**



Capture SHA-256: 953d9a1220a1b501a0ede3a87b7d5516c6552f0e0d727f3b59246c01ef255e3b

02

EXECUTED GHERKIN STEP

When I sign in to the redesign as a manufacturer PASS

 Technical file 

   [TEST] Northstar Medical Im...  

Your work

[TEST] Northstar Medical Imaging · Wednesday 9 September

 **7**
drafts to finish

 **0**
returned for changes

 **0**
waiting on a partner

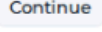
 **31**
devices, 5 released

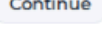
 Add a device

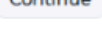
Needs you

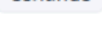
7 drafts

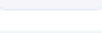
 **Northstar CardioMesh Coronary Stent**
1.0 first release 

 **Northstar LumaDerm Phototherapy Lamp**
Change 1 · first release 

 **Northstar SonoLite Handheld Ultrasound**
1.0 first release 

 **Northstar VitalSync Patient Monitor**
1.1 labelling update 

 **E2E Journey Device 1788933641806128**
Change 1 · 1.0.0 · first release 

 **E2E Journey Device 1788933703671839**
Change 1 · 1.0.0 · first release 

Devices · 31

 Name, UDI-DI or Basic UDI-DI

 **PulseView AR Validation ...** 

 **AtlasView AR Verification ...** 

 **AtlasView AR Validation ...** 

 **AtlasView Importer Verifi...** 

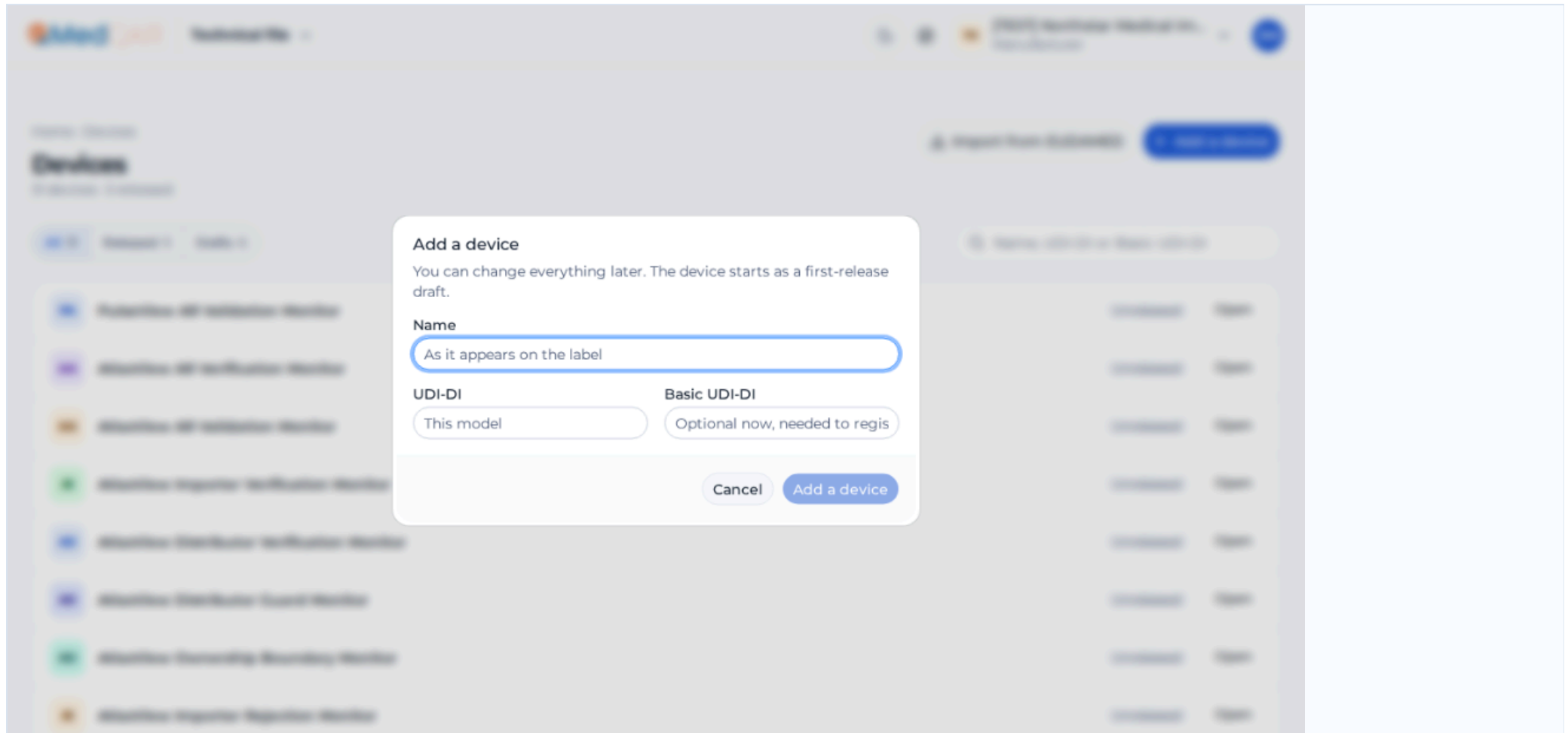
 **AtlasView Distributor Veri...** 

 **AtlasView Distributor Gu...** 

Capture SHA-256: 834b4b311d856e5742fd67cff9e02ea0e853e49d710895ceca2d73f4c25f54a1

03

EXECUTED GHERKIN STEP

And I open the redesign's add-device form **PASS**

Capture SHA-256: f44b15c0755232f27cdf7544ddac156a11373ff65a626493fdd2e01895725168

04

EXECUTED GHERKIN STEP

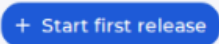
And I submit a device with a unique name and UDI-DI PASS

 Technical file 

  [TEST] Northstar Medical Im...  

Home > Devices > E2E Journey Device 1788933709697226

 **E2E Journey Device 1788933709697226** Unreleased
not released yet · Basic UDI-DI —

Choose who 

Changes and releases

No changes yet.

Registration Open

Not started. EUDAMED needs every answer.

Who can open it Choose who

Only you, so far.

Identification

UDI-DI
E2E-1788933709697226

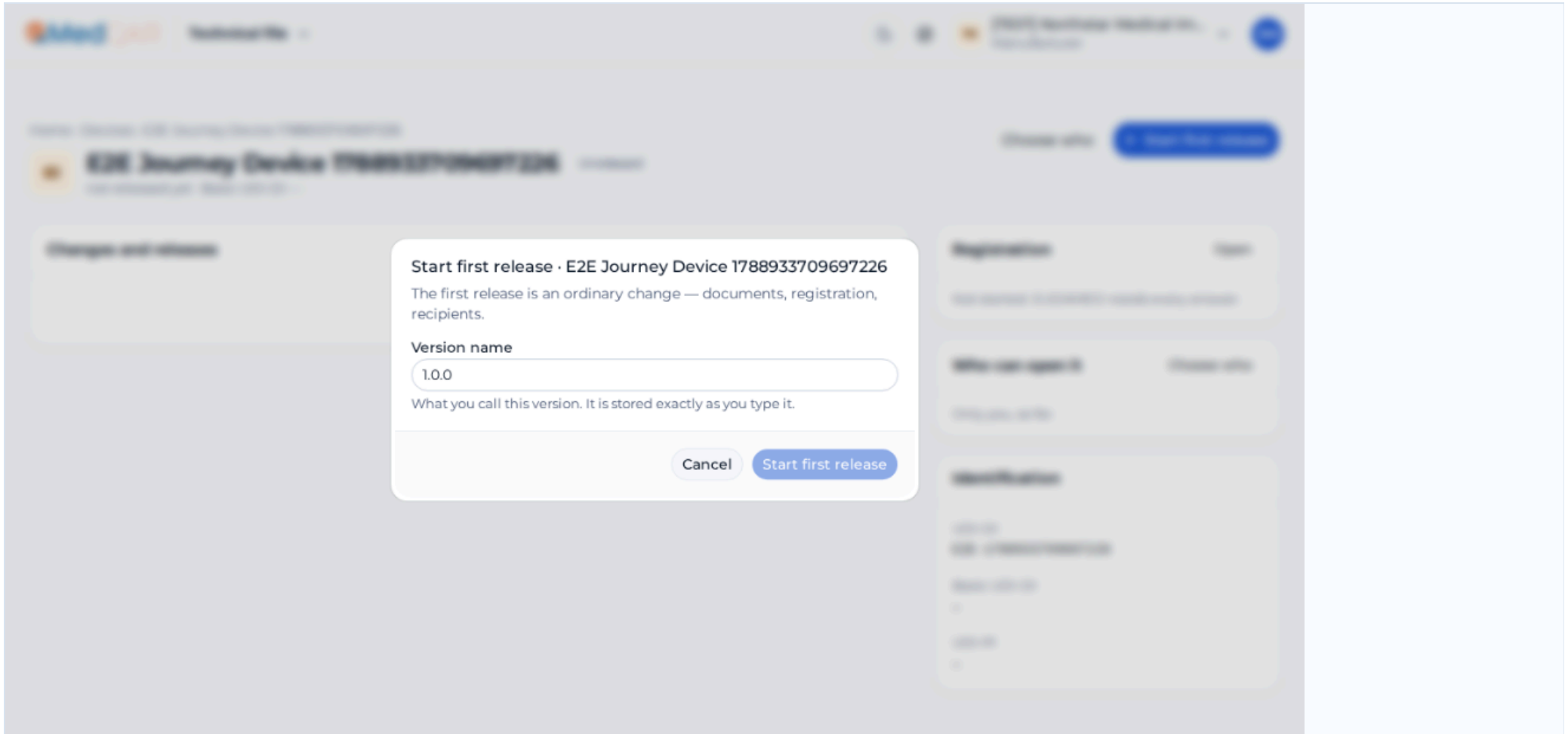
Basic UDI-DI
—

UDI-PI
—

Capture SHA-256: 8005a5d4870cc888867694ea6bd0b9c9d08f1785d3a27884b6131df861381b8e

05

EXECUTED GHERKIN STEP

And I start the device's first release PASS

Capture SHA-256: 75ab166bf918a1639edfaa6b48bd7d998b143d1913811b95606de9ee509060d8

06

EXECUTED GHERKIN STEP

And I upload a document to the change PASS

 Technical file ▼

↻ TN [TEST] Northstar Medical Im... ▼ EM
Manufacturer

Home › E2E Journey Device 1788933709697226 › Change 1

Discard draft Release

 **Change 1** Draft
Version 1.0.0 Rename

 **Documents** 1 · 1 changed Find Add files

 **Drop PDFs here** · section guessed from the filename, you confirm

 **IFU & labelling** 1 document

☐ multi-eo-product-label.pdf New 🔍 ...

Ready to release? Ready

✓ **Every upload has a section.**
Settings / Review policy · Documents

⚠ **This device's target market is not recorded — add its EUDAMED registration from the device's Registration page; the registration records the market.**
Who receives it · Release authority & reviewers · recommended — you can still release
MDIS compares your organisation's country (from its SRN) with this device's market. Your representative is appointed under Who receives it — a partner you are already connected to at once, a new one once they accept the invitation. Confirming records that the appointment covers this market.
[Open Who receives it](#)

Capture SHA-256: 31f8187e8072bcda72ccf765e1451ea223f0e8116549c72aa826c5ca1005543f

07 EXECUTED GHERKIN STEP
Then no upload is left needing a section PASS

No visible change at this step; the asserted state was already present

 **Technical file** 

  **[TEST] Northstar Medical Im...**  

Home › E2E Journey Device 1788933709697226 › Change 1

 **Change 1** Draft

Version 1.0.0 Rename

 **Documents** 1 · 1 changed

 Add files

 Drop PDFs here · section guessed from the filename, you confirm

 IFU & labelling

1 document

☐ multi-eo-product-label.pdf

New

Ready to release? Ready

 **Every upload has a section.**
Settings / Review policy · Documents

 **This device's target market is not recorded — add its EUDAMED registration from the device's Registration page; the registration records the market.**
Who receives it · Release authority & reviewers · recommended — you can still release
MDIS compares your organisation's country (from its SRN) with this device's market. Your representative is appointed under Who receives it — a partner you are already connected to at once, a new one once they accept the invitation. Confirming records that the appointment covers this market.
[Open Who receives it](#)

Capture SHA-256: 31f8187e8072bcda72ccf765e1451ea223f0e8116549c72aa826c5ca1005543f

JOURNEY CHAPTER

Release, review, deliver

A frozen release is reviewed by the configured roles, corrected when needed, and delivered after the final decision.

features/release-integration/round46-pdf-review-acceptance.feature · @VALIDATION-SUPPORTING @SR-030 @SR-031 @SR-032 @UR-002 @UR-005 @MODULE:RELEASE

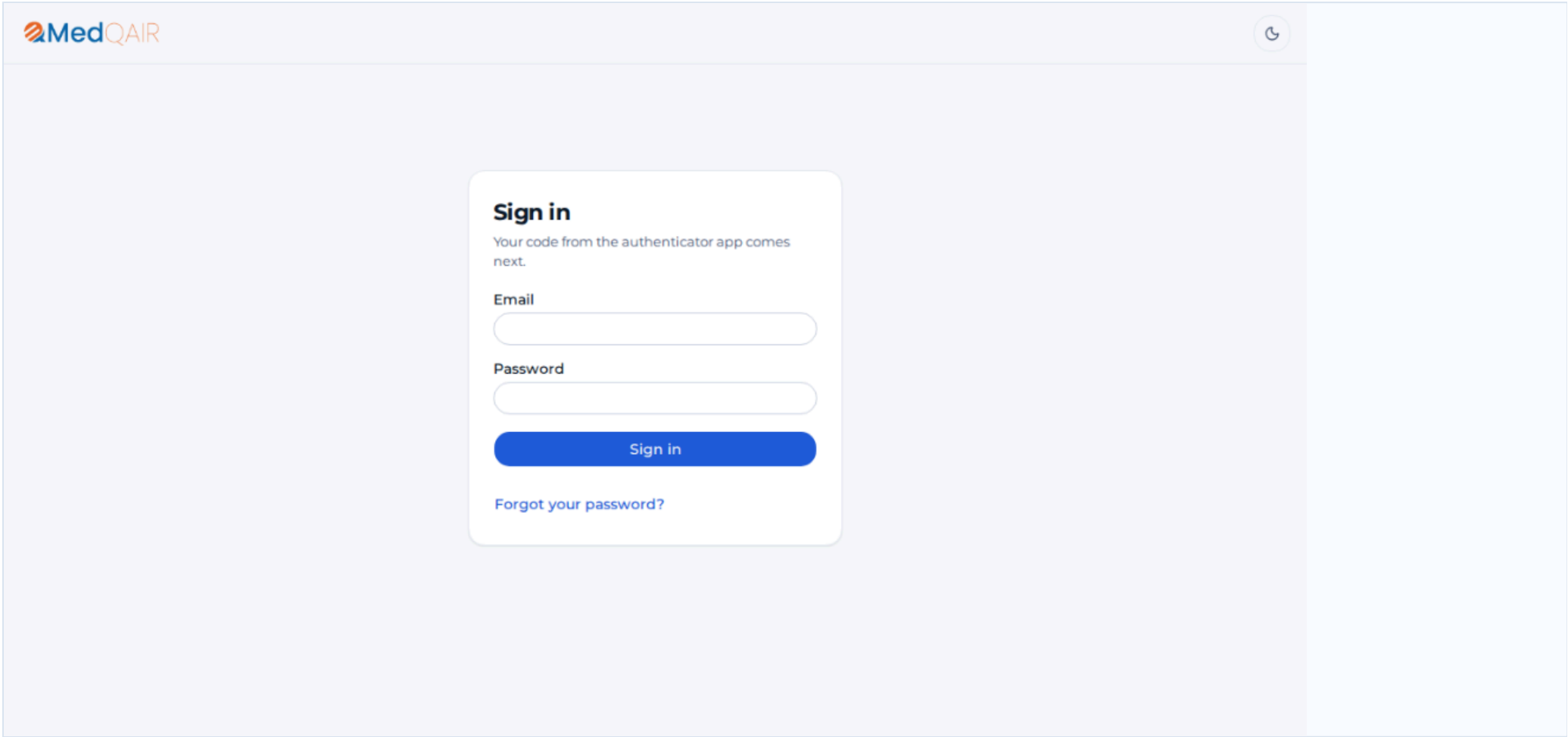
PASS

Approval of the exact frozen release completes delivery without a second Release press

01

EXECUTED GHERKIN STEP

Given the redesign sign-in page PASS



Capture SHA-256: 953d9a1220a1b501a0ede3a87b7d5516c6552f0e0d727f3b59246c01ef255e3b

02

EXECUTED GHERKIN STEP

When I sign in to the redesign as a manufacturer **PASS**

 Technical file 

   [TEST] Northstar Medical Im...  

Your work

[TEST] Northstar Medical Imaging · Wednesday 9 September

 **12**
drafts to finish

 **0**
returned for changes

 **0**
waiting on a partner

 **43**
devices, 8 released

 Add a device

Needs you

12 drafts

 **Northstar SonoLite Handheld Ultrasound**
1.0 first release 

 **Northstar VitalSync Patient Monitor**
1.1 labelling update 

 **Northstar CardioMesh Coronary Stent**
1.0 first release 

 **Northstar LumaDerm Phototherapy Lamp**
Change 1 · first release 

 **E2E Journey Device 1788933641806128**
Change 1 · 1.0.0 · first release 

 **E2E Journey Device 1788933703671839**
Change 1 · 1.0.0 · first release 

Devices · 43

 Name, UDI-DI or Basic UDI-DI

 **PulseView AR Validation ...** 

 **AtlasView AR Verification ...** 

 **AtlasView AR Validation ...** 

 **AtlasView Importer Verifi...** 

 **AtlasView Importer Rejec...** 

 **AtlasView Distributor Veri...** 

Capture SHA-256: 8095590cd5022eed9d36c1316220d814f7fa52aa347767b791a6e897e2d9193

03

EXECUTED GHERKIN STEP

And I open the device that already has partners PASS

 Technical file 

 TN [TEST] Northstar Medical Im...  EM

Home > Devices > ClearPath Release Monitor

CR

ClearPath Release Monitor Released

current Change 10 released 9 Sept · Basic UDI-DI 09506000900259

Choose who

+ Start a change

Changes and releases	Release history
 Change 10 Released 9 Sept	Delivered Open
 Change 9 Released 9 Sept	Delivered Open
 Change 8 Returned · documents only · edited 9 Sept	Returned Continue
 Change 7 Released 9 Sept	Delivered Open
 Change 6 Released 9 Sept	Delivered Open
 Change 5 Released 9 Sept	Delivered Open
 Changes requested — withdrawal exercise Released 9 Sept · withdrawn · never delivered	Withdrawn Open

Registration Open

All 65 answers · ready for EUDAMED XML

Who can open it Choose who

TH [TEST] Harborline Importers
All documents

TS [TEST] Sectra Distribution
Nothing yet · Distributor · since 2019

EA E2E Authorised Rep Co
Nothing yet · Authorised representative

Identification

UDI-DI
09506000900346

Capture SHA-256: 7fa1c8a1a4b8b3f6c83605ae3a85a7ba1d57419ce0ef53ec3d79f46b802d4012

04

EXECUTED GHERKIN STEP

And I start a follow-up change PASS

 Technical file [TEST] Northstar Medical Im... EM

Home ClearPath Release Monitor Change 11 Discard draft Release

CR

Change 11

Draft
follows Change 10 released 9 Sept

Documents 1 · 1 changed Find Add files

Drop PDFs here · section guessed from the filename, you confirm

Certificates & declarations 1 document

☐ Declaration of Conformity EN

Replaces previous

P1 corrected release [TEST] Harborline Im... 1788933979001

Ready to release?

Ready

- ✓ **Every upload has a section.**
Settings / Review policy · Documents
- ✓ **Your representation for this market is confirmed.**
Who receives it · Release authority & reviewers
- ✓ **Waiting for one approval after release**
E2E Authorised Rep Co · approval is required before delivery

Registration Checking...
Loading registration...
Open registration

Who receives it Choose who

Capture SHA-256: b22b0f3cdf13258572962b5d6a691832ba078f6d27b9c140a435771a077cd0aa

05

EXECUTED GHERKIN STEP

Then the further release carries the frozen document forward PASS

 **Technical file** 

  **[TEST] Northstar Medical Im...**  

Home > ClearPath Release Monitor > Change 11

CR **Change 11** Draft
follows Change 10 released 9 Sept

 **Documents** 1 · 1 changed  **Add files**

 **Drop PDFs here** · section guessed from the filename, you confirm

 **Certificates & declarations** 1 document

☐ **Declaration of Conformity** EN
Replaces previous

P1
corrected-
release [TEST] Harborline Im...
1788933979001

 ...

Ready to release? Ready

- ✓ **Every upload has a section.**
Settings / Review policy · Documents
- ✓ **Your representation for this market is confirmed.**
Who receives it · Release authority & reviewers
- ✓ **Waiting for one approval after release**
E2E Authorised Rep Co · approval is required before delivery

 **Registration** Unchanged

Registration matches the registered record.

Open registration

Capture SHA-256: 629c88d55722e68841ceaf19ea306d42b2d45238521504032d752f3d4d57838

06

EXECUTED GHERKIN STEP

When I configure the authorised representative as a blocking approver PASS

No visible change at this step; the blocking approver configuration remains visibly shown after setup

 **Technical file** 

 TN **[TEST] Northstar Medical Im...**  EM

Home > ClearPath Release Monitor > Change 11

CR

Change 11

Draft

follows Change 10 released 9 Sept

 **Documents** 1 · 1 changed

 Add files

 Drop PDFs here · section guessed from the filename, you confirm

 **Certificates & declarations**

1 document

☐ Declaration of Conformity EN

Replaces previous

P1

corrected-

release

[TEST] Harborline Im...





1788933979001

Ready to release? Ready

✓

Every upload has a section.

Settings / Review policy · Documents

✓

Your representation for this market is confirmed.

Who receives it · Release authority & reviewers

✓

Waiting for one approval after release

E2E Authorised Rep Co · approval is required before delivery

 **Registration** Unchanged

Registration matches the registered record.

Open registration

Capture SHA-256: 629c88d55722e68841ceae19ea306d42b2d45238521504032d752f3d4d57838

MDIS walkthrough · 36 / 418

07

EXECUTED GHERKIN STEP

And I press Release once for the tracked candidate PASS

 Technical file 

 TN [TEST] Northstar Medical Im...  EM

Home > ClearPath Release Monitor > Change 11

CR **Change 11** Draft
follows Change 10 released 9 Sept

 **Documents** 1 · 1 changed  Add files

 Drop PDFs here · section guessed from the filename, you confirm

 **Certificates & declarations** 1 document

☐ Declaration of Conformity EN
Replaces previous

P1
corrected-
release [TEST] Harborline Im...
1788933979001

 ...

Ready to release? Ready

- ✓ **Every upload has a section.**
Settings / Review policy · Documents
- ✓ **Your representation for this market is confirmed.**
Who receives it · Release authority & reviewers
- ✓ **Waiting for one approval after release**
E2E Authorised Rep Co · approval is required before delivery

 **Registration** Unchanged

Registration matches the registered record.

Open registration

Capture SHA-256: c71c0d3a5a8d960dd26d9be2ede157dd12bb9386ddce2cd36bea57f787f274cb

08

EXECUTED GHERKIN STEP

Then delivery is visibly waiting for its blocking decision **PASS**

 Technical file 

  [TEST] Northstar Medical Im...  

Home > ClearPath Release Monitor > Change 11

CR

Change 11

Waiting

follows Change 10 released 9 Sept

 **Documents** 1 · 1 changed · frozen as released

 **Certificates & declarations**

1 document

Declaration of Conformity 

Replaces previous

P1

corrected release

[TEST] Harborline Im...



...

1788933979001

 **Registration**

Unchanged

Registration matches the registered record.

Open registration

Who receives it Choose who

 **[TEST] Harborline Importers**

Importer · all 1 document · on delivery

Approvals, in order

1

E2E Authorised Rep Co

Approver · Asked now

Now



Delivery to 1 partner

Starts by itself on the last approval

Capture SHA-256: cfbae63497d217778ffcedc79574584e04088163df72902e446e6450d57c626

09

EXECUTED GHERKIN STEP

When I switch to the exact authorised representative **PASS**

MedQAIR Technical file ⌵ ⌚ @ EA E2E Authorised Rep Co ⌵ Authorised Representative EA

Your work

E2E Authorised Rep Co · Wednesday 9 September

✓ **3** releases to approve 📄 **10** devices shared with you

Needs you

NN	Northstar NeuroScan EEG Cap Approve the release · Review requested by [TEST] Northstar Medical Imaging	Approve
NO	Northstar OxyTrack Pulse Oximeter Approve the release · Approval requested by [TEST] Northstar Medical Imaging	Approve
CR	ClearPath Release Monitor Approve the release · Approval requested by [TEST] Northstar Medical Imaging	Approve

Devices · 10 All 10 >

Q Name, UDI-DI or Basic UDI-DI

PA	PulseView AR Validation ...	Unreleased
AA	AtlasView AR Verification ...	Unreleased
AA	AtlasView AR Validation ...	Unreleased
CR	ClearPath Release Monitor Candidate 1 released 9 Sept	Released
AM	AtlasView Multi-EO Release... Candidate 1 released 9 Sept	Released
EA	E2E Release Ledger Synthe...	Released

Capture SHA-256: 99bb2715d07cb399324fc533bc75e29ab013a9a6cc315dd02e34add7b53dfec9

10

EXECUTED GHERKIN STEP

And I open the tracked approval from the work queue PASS

 Technical file E2E Authorised Rep Co Authorised Representative

Your work > ClearPath Release Monitor > Change 11

CR **Approve the release** Waiting

[TEST] Northstar Medical Imaging · released 9 Sept · 1 document · your approval holds delivery · it starts by itself after the last one

Frozen release documents

1 document

PDF review Exact revision

Download

+

Multi-EO Product Label

Start a feedback thread

Whole document Page 1 Region

Capture SHA-256: 350b46b09db37175f93a1019a4e27d3a41d667a86794b9a63852d75321276409

11

EXECUTED GHERKIN STEP

And I approve the tracked release **PASS**

 Technical file 

  E2E Authorised Rep Co
Authorised Representative 

Start a feedback thread

Whole document ☐ Page 1 ☐ Region ☐

Blocks approval ☐ Note only ☐

Blocking findings go to the manufacturer with "Request changes". Notes travel with either decision and never hold anything.

Open thread

Your decision

Approver - E2E Authorised Rep Co

Your approval is your Article 11 verification of this release.

✓ Approve

 Request changes

Delivery starts by itself after the last approval.

Signed outside MDIS? optional

If your organisation signs its verification elsewhere, the reference is kept with this approval.

Recording...

Capture SHA-256: 7e7db031aae14d33e9618d9b7c85f7eaa8987de30fa72a070ca39a9dea5162be

12

EXECUTED GHERKIN STEP

Then the approval decision is durably recorded **PASS**

The screenshot shows the MedQAIR interface. The top navigation bar includes the MedQAIR logo, a 'Technical file' dropdown, a refresh icon, and a user profile for 'E2E Authorised Rep Co' with a dropdown arrow and a blue 'EA' badge. The main content area has a breadcrumb trail: 'Your work > ClearPath Release Monitor > Change 11'. Below this is a section titled 'Approve the release' with a 'CR' badge and a 'Delivered' status. A sub-header reads: '[TEST] Northstar Medical Imaging · released 9 Sept · 1 document · your approval is your verification of this release'. A large white box contains the message: 'Decision recorded. You approved this release. If you were the last approver, delivery has started by itself.' At the bottom of this box is a blue button labeled 'Back to your work'.

Capture SHA-256: def2a73e618e5ee33f9f739bc2ba8192e2e7970e49839e40b3967949ce86cc91

13

EXECUTED GHERKIN STEP

When I switch back to the manufacturer PASS

 Technical file 

   [TEST] Northstar Medical Im...  

Your work

[TEST] Northstar Medical Imaging · Wednesday 9 September

 **12**
drafts to finish

 **0**
returned for changes

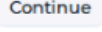
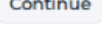
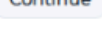
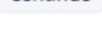
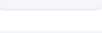
 **0**
waiting on a partner

 **43**
devices, 8 released

 Add a device

Needs you

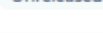
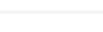
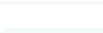
12 drafts

	Northstar SonoLite Handheld Ultrasound 1.0 first release	
	Northstar VitalSync Patient Monitor 1.1 labelling update	
	Northstar CardioMesh Coronary Stent 1.0 first release	
	Northstar LumaDerm Phototherapy Lamp Change 1 · first release	
	E2E Journey Device 1788933641806128 Change 1 · 1.0.0 · first release	
	E2E Journey Device 1788933703671839 Change 1 · 1.0.0 · first release	

Devices · 43

All 43 >

 Name, UDI-DI or Basic UDI-DI

	PulseView AR Validation ...	
	AtlasView AR Verification ...	
	AtlasView AR Validation ...	
	AtlasView Importer Verifi...	
	AtlasView Importer Rejec...	
	AtlasView Distributor Veri...	

Capture SHA-256: 8095590cd5022eed9d36c1316220d814f7fa52aa347767b791a6e897e2d9193

14

EXECUTED GHERKIN STEP

And I reopen the tracked release PASS

 **Technical file** 

 TN **[TEST] Northstar Medical Im...**  EM

Home > ClearPath Release Monitor > Change T1

CR

Change T1 Delivered

on the market since 9 Sept

 **Documents** 1 · 1 changed · frozen as released

 **Certificates & declarations**

1 document

Declaration of Conformity EN

Replaces previous

P1

corrected release

[TEST] Harborline Im...

 ...

1788933979001

 **Registration** Unchanged

Registration matches the registered record.

Open registration

Who receives it Choose who

TH **[TEST] Harborline Importers**

Importer · all 1 document

Approvals, in order

 **E2E Authorised Rep Co**

Approver · Approved 9 Sept

 **Delivery**

Delivered on 2026-09-09.

Capture SHA-256: fd9999d9672ae8e3901144d35c7e32b94ccc2b0d971817bf9f1435f09a628e50

15

EXECUTED GHERKIN STEP

Then the tracked release is delivered without another Release action PASS

No visible change at this step; the delivered projection remains visibly shown without another Release action

 **Technical file** 

 TN **[TEST] Northstar Medical Im...**  EM

Home > ClearPath Release Monitor > Change T1

CR

Change T1 Delivered

on the market since 9 Sept

 **Documents** 1 · 1 changed · frozen as released

 **Certificates & declarations**

1 document

Declaration of Conformity

EN

Replaces previous

P1

corrected-

release

[TEST] Harborline Im...

1788933979001

 **Registration** Unchanged

Registration matches the registered record.

Open registration

Who receives it Choose who

TH **[TEST] Harborline Importers**

Importer · all 1 document

Approvals, in order

 **E2E Authorised Rep Co**

Approver · Approved 9 Sept

 **Delivery**

Delivered on 2026-09-09.

Capture SHA-256: fd9999d9672ae8e3901144d35c7e32b94ccc2b0d971817bf9f1435f09a628e50

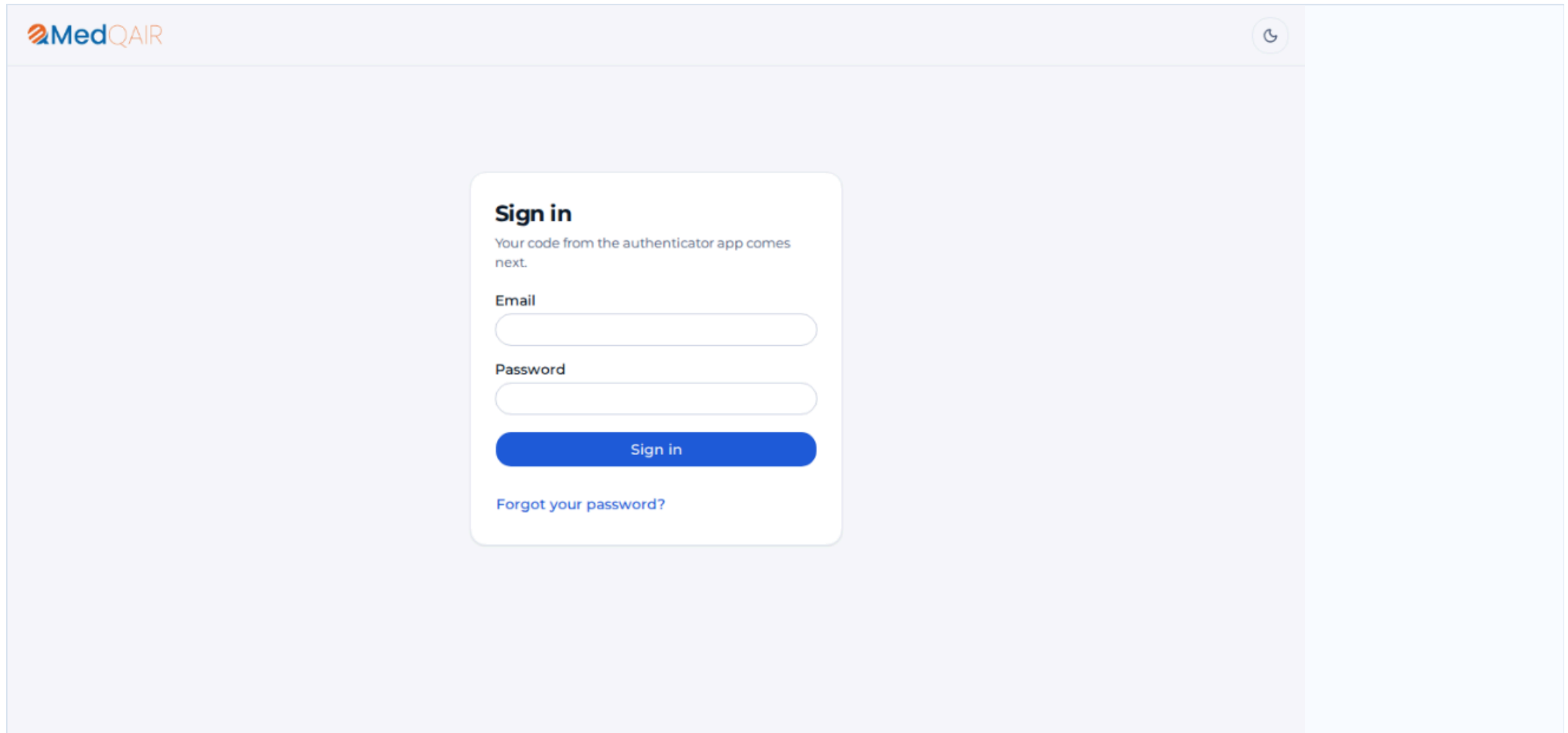
MDIS walkthrough · 45 / 418

The authorised representative's approval is its Article 11 verification and cites an outside signature

01

EXECUTED GHERKIN STEP

Given the redesign sign-in page **PASS**



Capture SHA-256: 953d9a1220a1b501a0ede3a87b7d5516c6552f0e0d727f3b59246c01ef255e3b

02

EXECUTED GHERKIN STEP

When I sign in to the redesign as a manufacturer **PASS**

 Technical file 

   [TEST] Northstar Medical Im...  

Your work

[TEST] Northstar Medical Imaging · Wednesday 9 September

 **12**
drafts to finish

 **0**
returned for changes

 **0**
waiting on a partner

 **41**
devices, 6 released

 Add a device

Needs you

12 drafts

 **Northstar VitalSync Patient Monitor**
1.1 labelling update 

 **Northstar SonoLite Handheld Ultrasound**
1.0 first release 

 **Northstar CardioMesh Coronary Stent**
1.0 first release 

 **Northstar LumaDerm Phototherapy Lamp**
Change 1 · first release 

 **E2E Journey Device 1788933641806128**
Change 1 · 1.0.0 · first release 

 **E2E Journey Device 1788933703671839**
Change 1 · 1.0.0 · first release 

Devices · 41

 Name, UDI-DI or Basic UDI-DI

 **PulseView AR Validation ...** 

 **AtlasView PRRC Validatio...** 

 **AtlasView AR Verification ...** 

 **AtlasView AR Validation ...** 

 **AtlasView Importer Verifi...** 

 **AtlasView Importer Rejec...** 

Capture SHA-256: 2635fc1c93d52d0a66885acc0e57e65bb091a15eb467f6eff4e140170fab9ef9

03

EXECUTED GHERKIN STEP

And I open the device that already has partners PASS

 Technical file 

  TN [TEST] Northstar Medical Im...  EM

Home > Devices > ClearPath Release Monitor

CR

ClearPath Release Monitor Released

current Changes requested — withdrawal exercise released 9 Sept · Basic UDI-DI 09506000900259

Choose who

+ Start a change

Changes and releases

Release history

 **Changes requested — withdrawal exercise**
Returned · documents only · edited 9 Sept

ReturnedContinue

 **Changes requested by the AR**
Returned · documents only · edited 9 Sept

ReturnedContinue

 **Awaiting AR review**
Released 9 Sept · waiting for approval

WaitingOpen

 **1.0**
Released 9 Sept · FIX-REL-CLEAN registered baseline

DeliveredOpen

Current file Changes requested — withdrawal exercise · 1 document

Find

 **Certificates & declarations**

1 document

Declaration of Conformity · en

approved-baseline

RegistrationOpen

All 65 answers · ready for EUDAMED XML

Who can open itChoose who

TH

[TEST] Harborline Importers
All documents

TS

[TEST] Sectra Distribution
Nothing yet · Distributor · since 2019

EA

E2E Authorised Rep Co
Nothing yet · Authorised representative

Identification

UDI-DI
09506000900346

Capture SHA-256: 572a5c0282b404e13399cb07927e530b2b0d6ce47262f21776a4fc60650cf3c3

04

EXECUTED GHERKIN STEP

And I start a follow-up change PASS

 **Technical file** 

  **[TEST] Northstar Medical Im...**  

Home > ClearPath Release Monitor > Change 5

CR

Change 5

Draft

follows Changes requested — withdrawal exercise released 9 Sept

 **Documents** 1

 **Add files**

 **Drop PDFs here** · section guessed from the filename, you confirm

1 unchanged documents [Show all](#)

Ready to release? Ready

 **Every upload has a section.**
Settings / Review policy · Documents

 **Your representation for this market is confirmed.**
Who receives it · Release authority & reviewers

 **Waiting for one approval after release**
E2E Authorised Rep Co · approval is required before delivery

 **Registration** Unchanged

Registration matches the registered record.

[Open registration](#)

Capture SHA-256: 1c3b13f4935a80f15769d9be2cc649f92d088b332b2f93b76040eb72429ccad8

05

EXECUTED GHERKIN STEP

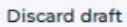
Then the further release carries the frozen document forward **PASS**

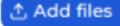
 Technical file 

  [TEST] Northstar Medical Im...  

Home > ClearPath Release Monitor > Change 5

 **Change 5** Draft
follows Changes requested — withdrawal exercise released 9 Sept

 Documents 1 

 Drop PDFs here · section guessed from the filename, you confirm

 Certificates & declarations 1 document

☐ Declaration of Conformity  approved-baseLine [TEST] Harborline Im...  ...

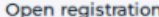
Showing 1 unchanged documents [Hide](#)

Ready to release? 

 **Every upload has a section.**
Settings / Review policy · Documents

 **Your representation for this market is confirmed.**
Who receives it · Release authority & reviewers

 **Waiting for one approval after release**
E2E Authorised Rep Co · approval is required before delivery

 **Registration** 
Registration matches the registered record.


Capture SHA-256: 647a7a0b2d9175127851f9a7db77ece4f46eed2e9fb34b9addcc6a7182b8dd9b

06

EXECUTED GHERKIN STEP

When I configure the authorised representative as a blocking approver PASS

No visible change at this step; the blocking approver configuration remains visibly shown after setup

The screenshot displays the MedQAIR 'Technical file' interface. At the top, the MedQAIR logo is on the left, and a dropdown menu shows '[TEST] Northstar Medical Im...' with a 'TN' icon and an 'EM' icon. The main header area includes a breadcrumb 'Home > ClearPath Release Monitor > Change 5' and two buttons: 'Discard draft' and 'Release'. Below this, a section titled 'Change 5' with a 'Draft' status and a 'CR' icon is shown, with a note 'follows Changes requested — withdrawal exercise released 9 Sept'. The main content area is divided into two columns. The left column has a 'Documents' section with a 'Find' input and an 'Add files' button, followed by a 'Drop PDFs here' instruction. Below this is a 'Certificates & declarations' section with '1 document'. A table lists a document: 'Declaration of Conformity' (EN), 'approved-baseline', '[TEST] Harborline Im...', with an eye icon and a menu icon. It notes 'Showing 1 unchanged documents' and a 'Hide' link. The right column has a 'Ready to release?' section with a 'Ready' status. It contains three checklist items: 'Every upload has a section.' (Settings / Review policy · Documents), 'Your representation for this market is confirmed.' (Who receives it · Release authority & reviewers), and 'Waiting for one approval after release' (E2E Authorised Rep Co · approval is required before delivery). Below this is a 'Registration' section with an 'Unchanged' status, stating 'Registration matches the registered record.' and an 'Open registration' button.

MedQAIR Technical file

Home > ClearPath Release Monitor > Change 5

CR **Change 5** Draft
follows Changes requested — withdrawal exercise released 9 Sept

Discard draft Release

Documents 1 Find Add files

Drop PDFs here · section guessed from the filename, you confirm

Certificates & declarations 1 document

☐ Declaration of Conformity EN	approved-baseline	[TEST] Harborline Im...	👁	⋮
---	-------------------	-------------------------	---	---

Showing 1 unchanged documents Hide

Ready to release? Ready

- ✓ Every upload has a section.
Settings / Review policy · Documents
- ✓ Your representation for this market is confirmed.
Who receives it · Release authority & reviewers
- ✓ Waiting for one approval after release
E2E Authorised Rep Co · approval is required before delivery

Registration Unchanged

Registration matches the registered record.

Open registration

Capture SHA-256: 647a7a0b2d9175127851f9a7db77ece4f46eed2e9fb34b9addcc6a7182b8dd9b

07

EXECUTED GHERKIN STEP

And I press Release once for the tracked candidate **PASS**

The screenshot displays the MedQAIR 'Technical file' interface for a specific change. At the top, the MedQAIR logo is on the left, and the file name '[TEST] Northstar Medical Im...' is on the right. Below the header, the breadcrumb 'Home > ClearPath Release Monitor > Change 5' is visible. The main section is titled 'Change 5' with a 'Draft' status and a note 'follows Changes requested — withdrawal exercise released 9 Sept'. To the right of this section are two buttons: 'Discard draft' and 'Releasing...'. Below the title, there are two main panels. The left panel, 'Documents', shows a 'Drop PDFs here' area and a list of 'Certificates & declarations' with one document, 'Declaration of Conformity', which is marked as 'approved-baseLine'. The right panel, 'Ready to release?', shows a 'Ready' status and three checkmarks indicating that the upload has a section, the representation is confirmed, and one approval is required after release. Below this, a 'Registration' section shows that the registration matches the registered record.

MedQAIR Technical file

Home > ClearPath Release Monitor > Change 5

Change 5 Draft
follows Changes requested — withdrawal exercise released 9 Sept

Discard draft Releasing...

Documents 1 Find Add files

Drop PDFs here · section guessed from the filename, you confirm

Certificates & declarations 1 document

☐ Declaration of Conformity EN approved-baseLine [TEST] Harborline Im... ...

Showing 1 unchanged documents Hide

Ready to release? Ready

- ✓ Every upload has a section.
Settings / Review policy · Documents
- ✓ Your representation for this market is confirmed.
Who receives it · Release authority & reviewers
- ✓ Waiting for one approval after release
E2E Authorised Rep Co · approval is required before delivery

Registration Unchanged
Registration matches the registered record.
Open registration

Capture SHA-256: e1bf23020b35900b38b3feaa36139a59e38b170091f88ca3d536ab58264af091

08

EXECUTED GHERKIN STEP

Then delivery is visibly waiting for its blocking decision PASS

 Technical file 

  [TEST] Northstar Medical Im...  

Home > ClearPath Release Monitor > Change 5

CR

Change 5 Waiting

follows Change 5 released 9 Sept

 **Documents** 1 · frozen as released

 **Certificates & declarations**

1 document

Declaration of Conformity 

approved-baseLine [TEST] Harborline Im...  ...

Showing 1 unchanged documents [Hide](#)

 **Registration** Unchanged

Registration matches the registered record.

[Open registration](#)

Who receives it Choose who

 [TEST] Harborline Importers

Importer · all 1 document · on delivery

Approvals, in order

1 **E2E Authorised Rep Co** Now

Approver · Asked now

 **Delivery to 1 partner**

Starts by itself on the last approval

Capture SHA-256: 84c857d5591c322e88b274c21b898f518a79a509805724de16fd386875e7cbe7

09

EXECUTED GHERKIN STEP

When I switch to the exact authorised representative PASS

 Technical file 

  EA E2E Authorised Rep Co
Authorised Representative EA

Your work

E2E Authorised Rep Co · Wednesday 9 September

 **4**
releases to approve

 **10**
devices shared with you

Needs you

CR	ClearPath Release Monitor Approve the release · Approval requested by [TEST] Northstar Medical Imaging	Approve
NN	Northstar NeuroScan EEG Cap Approve the release · Review requested by [TEST] Northstar Medical Imaging	Approve
NO	Northstar OxyTrack Pulse Oximeter Approve the release · Approval requested by [TEST] Northstar Medical Imaging	Approve
CR	ClearPath Release Monitor Approve the release · Approval requested by [TEST] Northstar Medical Imaging	Approve

Devices · 10

[All 10 >](#)

 Name, UDI-DI or Basic UDI-DI

PA	PulseView AR Validation ...	Unreleased
AA	AtlasView AR Verification ...	Unreleased
AA	AtlasView AR Validation ...	Unreleased
CR	ClearPath Release Monitor Candidate 1 released 9 Sept	Released
AM	AtlasView Multi-EO Release... 1.2 PRRC as an ordered approve...	Released
EA	E2E Release Ledger Synthe...	Released

 Add a device

Capture SHA-256: 8f92ced506185444781d9308c579be167ef51d50a641380dc57e8e358a9c4fb3

10

EXECUTED GHERKIN STEP

And I open the tracked approval from the work queue PASS

 Technical file E2E Authorised Rep Co Authorised Representative

Your work > ClearPath Release Monitor > Change 5

CR **Approve the release** Waiting

[TEST] Northstar Medical Imaging · released 9 Sept · 1 document · your approval holds delivery · it starts by itself after the last one

Frozen release documents

1 document

PDF review

Exact revision

Download

+

Northstar Medical Imaging sample Instructions for Use

Capture SHA-256: 6eaf3c09594a51b33b9d9912149928726ab2a91df0591e51d1fe57a5d3acbad6

11

EXECUTED GHERKIN STEP

Then my own row says my approval is my Article 11 verification of this release

PASS

No visible change at this step; the Article 11 verification row remains visibly shown

 **Technical file** 



EA

E2E Authorised Rep Co

Authorised Representative

EA

Your work > ClearPath Release Monitor > Change 5

CR

Approve the release

Waiting

[TEST] Northstar Medical Imaging · released 9 Sept · 1 document · your approval holds delivery · it starts by itself after the last one

Frozen release documents

1 document

PDF review

Exact revision

Download

+

Northstar Medical Imaging sample Instructions for Use

Capture SHA-256: 6eaf3c09594a51b33b9d9912149928726ab2a91df0591e51d1fe57a5d3acbad6

12

EXECUTED GHERKIN STEP

When I approve the tracked release citing the outside signature "DocuSign envelope 4f2a-11" PASS

 Technical file 

  E2E Authorised Rep Co
Authorised Representative  

Start a feedback thread

Whole document

Page 1

Region

Describe what needs attention

Blocks approval

Note only

Blocking findings go to the manufacturer with "Request changes". Notes travel with either decision and never hold anything.

Open thread

Your decision

Approver - E2E Authorised Rep Co

Your approval is your Article 11 verification of this release.

✓ Approve

 Request changes

Delivery starts by itself after the last approval.

Signed outside MDIS? optional

DocuSign envelope 4f2a-11

If your organisation signs its verification elsewhere, the reference is kept with this approval.

Recording...

Capture SHA-256: 913f2fccac0576dcae385a3e51219aa552655b4f084f19bde544886789b5d7df

13

EXECUTED GHERKIN STEP

Then the approval decision is durably recorded **PASS**

The screenshot shows the MedQAIR interface. At the top left is the MedQAIR logo and a 'Technical file' dropdown. At the top right is a user profile for 'E2E Authorised Rep Co' with a refresh icon and a dropdown arrow. The main content area has a breadcrumb 'Your work > ClearPath Release Monitor > Change 5'. Below this is a section titled 'Approve the release' with a 'CR' icon and a 'Delivered' status. A message states: '[TEST] Northstar Medical Imaging · released 9 Sept · 1 document · your approval is your verification of this release'. A white box contains the message 'Decision recorded.' followed by 'You approved this release. If you were the last approver, delivery has started by itself.' and a 'Back to your work' button.

MedQAIR Technical file

EA E2E Authorised Rep Co Authorised Representative EA

Your work > ClearPath Release Monitor > Change 5

CR Approve the release Delivered

[TEST] Northstar Medical Imaging · released 9 Sept · 1 document · your approval is your verification of this release

Decision recorded.

You approved this release. If you were the last approver, delivery has started by itself.

Back to your work

Capture SHA-256: 0a5b9818bbea90ea6dca61a999e6ffedc4015a31a301df08e10fce2a88036ea3

14

EXECUTED GHERKIN STEP

When I switch back to the manufacturer PASS

 Technical file 

 TN [TEST] Northstar Medical Im...  EM

Manufacture

Your work

[TEST] Northstar Medical Imaging · Wednesday 9 September

 **12**
drafts to finish

 **0**
returned for changes

 **0**
waiting on a partner

 **41**
devices, 6 released

Needs you

12 drafts

 **Northstar VitalSync Patient Monitor**
1.1 labelling update

 **Northstar SonoLite Handheld Ultrasound**
1.0 first release

 **Northstar CardioMesh Coronary Stent**
1.0 first release

 **Northstar LumaDerm Phototherapy Lamp**
Change 1 · first release

 **E2E Journey Device 1788933641806128**
Change 1 · 1.0.0 · first release

 **E2E Journey Device 1788933703671839**
Change 1 · 1.0.0 · first release

Devices · 41

All 41 >

 **PulseView AR Validation ...**

Unreleased

 **AtlasView PRRC Validatio...**

Unreleased

 **AtlasView AR Verification ...**

Unreleased

 **AtlasView AR Validation ...**

Unreleased

 **AtlasView Importer Verifi...**

Unreleased

 **AtlasView Importer Rejec...**

Unreleased

Capture SHA-256: 2635fc1c93d52d0a66885acc0e57e65bb091a15eb467f6eff4e140170fab9ef9

MDIS walkthrough · 59 / 418

15

EXECUTED GHERKIN STEP

And I reopen the tracked release **PASS**

 **Technical file** 

  **[TEST] Northstar Medical Im...**  

Home > ClearPath Release Monitor > Change 5

CR **Change 5** **Delivered**
on the market since 9 Sept

Documents 1 · frozen as released

1 unchanged documents [Show all](#)

Registration **Unchanged**
Registration matches the registered record.
[Open registration](#)

Who receives it Choose who
 **[TEST] Harborline Importers**
Importer · all 1 document

Approvals, in order
 **E2E Authorised Rep Co**
Approver · Approved 9 Sept

 **Delivery**
Delivered on 2026-09-09.

Delivered to the frozen recipient set

Capture SHA-256: aaad0718a60157d97ab620b3fec2bbc69742fed56054ea3f83dedf57ca8cdd71

16

EXECUTED GHERKIN STEP

Then the tracked release is delivered without another Release action PASS*No visible change at this step; the delivered projection remains visibly shown without another Release action*

 **Technical file** 

  **[TEST] Northstar Medical Im...**  

Home > ClearPath Release Monitor > Change 5

Delivered to the frozen recipient set

 **Change 5** Delivered
on the market since 9 Sept

 **Documents** 1 · frozen as released

1 unchanged documents [Show all](#)

 **Registration** Unchanged
Registration matches the registered record.
[Open registration](#)

Who receives it [Choose who](#)
 **[TEST] Harborline Importers**
Importer · all 1 document

Approvals, in order
 **E2E Authorised Rep Co**
Approver · Approved 9 Sept

 **Delivery**
Delivered on 2026-09-09.

Capture SHA-256: aaad0718a60157d97ab620b3fec2bbc69742fed56054ea3f83dedf57ca8cdd71

17

EXECUTED GHERKIN STEP

And the recorded approval carries the outside signature "DocuSign envelope 4f2a-11" PASS*No visible change at this step; asserted through the API read*

The screenshot displays the MedQAIR Technical file interface. At the top, the MedQAIR logo is on the left, and a 'Technical file' dropdown menu is next to it. On the right, there are navigation icons, a 'TN' (Northstar Medical Im...) dropdown, and an 'EM' (Manufacturer) dropdown. The main content area shows the breadcrumb 'Home > ClearPath Release Monitor > Change 5'. Below this, a 'Change 5' card is marked 'Delivered' and notes it has been 'on the market since 9 Sept'. To the right of the card, it says 'Delivered to the frozen recipient set'. Below the card, there is a 'Documents' section with a 'Find' button and a 'Show all' link. The 'Documents' section shows '1 frozen as released' and '1 unchanged documents'. To the right of the documents, there are three sections: 'Registration' (marked 'Unchanged') with a description 'Registration matches the registered record.' and an 'Open registration' button; 'Who receives it' (marked 'Choose who') with a list of recipients including '[TEST] Harborline Importers' (Importer - all 1 document); and 'Approvals, in order' with a list of approvers including 'E2E Authorised Rep Co' (Approver - Approved 9 Sept). At the bottom, there is a 'Delivery' section showing 'Delivered on 2026-09-09.'

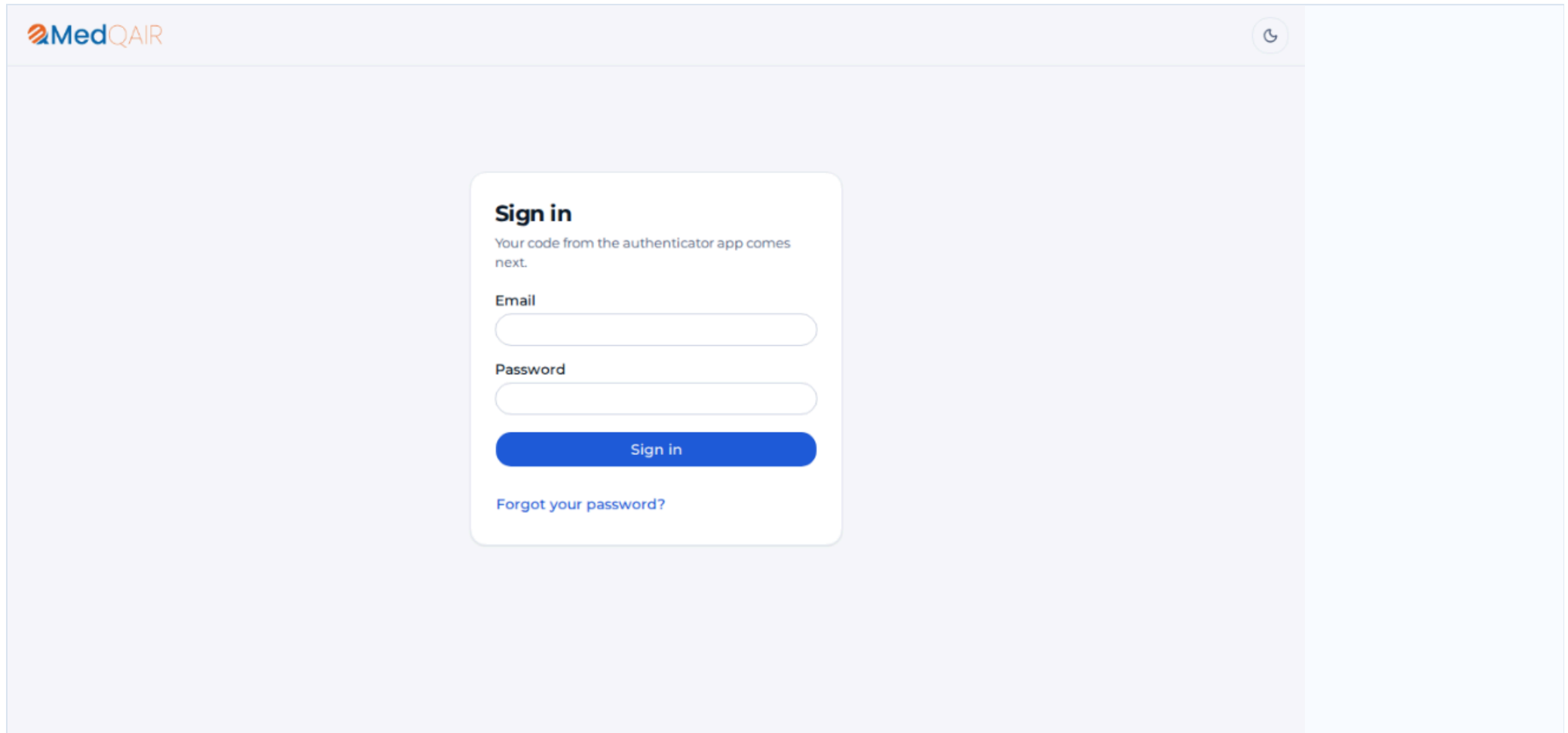
Capture SHA-256: aaad0718a60157d97ab620b3fec2bbc69742fed56054ea3f83dedf57ca8cdd71

The importer and the distributor are asked at delivery, decide, and hold nothing

01

EXECUTED GHERKIN STEP

Given the redesign sign-in page **PASS**



Capture SHA-256: 953d9a1220a1b501a0ede3a87b7d5516c6552f0e0d727f3b59246c01ef255e3b

02

EXECUTED GHERKIN STEP

When I sign in to the redesign as a manufacturer **PASS**

 Technical file 

   [TEST] Northstar Medical Im...  

Your work

[TEST] Northstar Medical Imaging · Wednesday 9 September

 **12**
drafts to finish

 **0**
returned for changes

 **0**
waiting on a partner

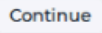
 **41**
devices, 6 released

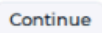
 Add a device

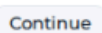
Needs you

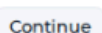
12 drafts

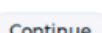
 **Northstar VitalSync Patient Monitor**
1.1 labelling update 

 **Northstar SonoLite Handheld Ultrasound**
1.0 first release 

 **Northstar CardioMesh Coronary Stent**
1.0 first release 

 **Northstar LumaDerm Phototherapy Lamp**
Change 1 · first release 

 **E2E Journey Device 1788933641806128**
Change 1 · 1.0.0 · first release 

 **E2E Journey Device 1788933703671839**
Change 1 · 1.0.0 · first release 

Devices · 41

 Name, UDI-DI or Basic UDI-DI

 **PulseView AR Validation ...** 

 **AtlasView PRRC Validatio...** 

 **AtlasView AR Verification ...** 

 **AtlasView AR Validation ...** 

 **AtlasView Importer Verifi...** 

 **AtlasView Importer Rejec...** 

Capture SHA-256: 2635fc1c93d52d0a66885acc0e57e65bb091a15eb467f6eff4e140170fab9ef9

03

EXECUTED GHERKIN STEP

And I select the release-native manufacturer context PASS

No visible change at this step; the authenticated release workspace remains visible after context selection

The screenshot displays the MedQAIR 'Technical file' workspace. At the top, the header includes the MedQAIR logo, a dropdown menu set to 'Technical file', and user information for '[TEST] Northstar Medical Im...' with a role of 'Manufacturer'. Below the header, the 'Your work' section shows a date filter for 'Wednesday 9 September' and a '+ Add a device' button. A summary row contains four cards: '12 drafts to finish', '0 returned for changes', '0 waiting on a partner', and '41 devices, 6 released'. The main content is divided into two panels. The 'Needs you' panel (12 drafts) lists items for review, including 'Northstar VitalSync Patient Monitor' (1.1 labelling update), 'Northstar SonoLite Handheld Ultrasound' (1.0 first release), 'Northstar CardioMesh Coronary Stent' (1.0 first release), 'Northstar LumaDerm Phototherapy Lamp' (Change 1 - first release), and two 'E2E Journey Device' entries. Each item has a 'Continue' button. The 'Devices · 41' panel (All 41) features a search bar and a list of devices, all marked as 'Unreleased', including 'PulseView AR Validation ...', 'AtlasView PRRC Validatio...', 'AtlasView AR Verification ...', 'AtlasView AR Validation ...', 'AtlasView Importer Verifi...', and 'AtlasView Importer Rejec...'.

Needs you	12 drafts
NV Northstar VitalSync Patient Monitor 1.1 labelling update	Continue
NS Northstar SonoLite Handheld Ultrasound 1.0 first release	Continue
NC Northstar CardioMesh Coronary Stent 1.0 first release	Continue
NL Northstar LumaDerm Phototherapy Lamp Change 1 - first release	Continue
E E2E Journey Device 1788933641806128 Change 1 - 1.0.0 - first release	Continue
E E2E Journey Device 1788933703671839 Change 1 - 1.0.0 - first release	Continue

Devices · 41	All 41 >
Q Name, UDI-DI or Basic UDI-DI	
PA PulseView AR Validation ...	Unreleased
AP AtlasView PRRC Validatio...	Unreleased
AA AtlasView AR Verification ...	Unreleased
AA AtlasView AR Validation ...	Unreleased
AI AtlasView Importer Verifi...	Unreleased
AI AtlasView Importer Rejec...	Unreleased

Capture SHA-256: 2635fc1c93d52d0a66885acc0e57e65bb091a15eb467f6eff4e140170fab9ef9

04

EXECUTED GHERKIN STEP

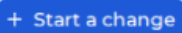
And I open the current multi-EO release device **PASS**

 Technical file 

  [TEST] Northstar Medical Im...  

Home > Devices > AtlasView Multi-EO Release Monitor

 **AtlasView Multi-EO Release Monitor**  Released
current 1.2 PRRC as an ordered approver released 9 Sept · Basic UDI-DI 0950600090035B

Choose who 

Changes and releases

Release history

 **1.2 PRRC as an ordered approver**
Released 9 Sept · Change 1  Open

Current file 1.2 PRRC as an ordered approver · 2 documents

 IFU & labelling 2 documents

ifu-multilingual.pdf

multi-eo-product-label.pdf

Registration

Open

28 of 65 answers · EUDAMED XML needs all 65

Who can open it

Choose who

 **E2E Authorised Rep Co**
Nothing yet · Authorised representative

 **[TEST] Harborline Importers**
All documents

 **[TEST] Sectra Distribution**
All documents

 **[TEST] Sectra Distribution**
Nothing yet · Distributor · since 2100

 **[TEST] Harborline Importers**
Nothing yet · Importer · since 2019

Capture SHA-256: 40f437dc0519df537613966076a99775295ca3deb6af0e99b3fc1a40b12a8a1a

05

EXECUTED GHERKIN STEP

And I start production version "1.3 importer and distributor as reviewers" PASS

 Technical file 

  [TEST] Northstar Medical Im...  

Home > AtlasView Multi-EO Release Monitor > Change 2

AM

Change 2 Draft

Version 1.3 importer and distributor as reviewers follows 1.2 PRRC as an ordered approver released 9 Sept [Rename](#)

 **Documents** 2

 Add files

 Drop PDFs here · section guessed from the filename, you confirm

2 unchanged documents [Show all](#)

Ready to release? Ready

 **Every upload has a section.**
Settings / Review policy · Documents

 **Your organisation's country is not this device's market, so the release needs a confirmed authorised representative — appoint one under Who receives it, then confirm.**
Who receives it · Release authority & reviewers · recommended — you can still release
MDIS compares your organisation's country (from its SRN) with this device's market. Your representative is appointed under Who receives it — a partner you are already connected to at once, a new one once they accept the invitation. Confirming records that the appointment covers this market.
[Confirm the appointment](#)
[Open Who receives it](#)

Capture SHA-256: 12a8313996164223fab08d03cf7ea721638c84c622a17e0e0fc8bbef085cee5c

06

EXECUTED GHERKIN STEP

And I ensure the current release has two documents PASS

 Technical file 

  [TEST] Northstar Medical Im...  

Home > AtlasView Multi-EO Release Monitor > Change 2

AM

Change 2 Draft

Version 1.3 importer and distributor as reviewers follows 1.2 PRRC as an ordered approver released 9 Sept [Rename](#)

 **Documents** 2

 Add files

 Drop PDFs here · section guessed from the filename, you confirm

 IFU & labelling

2 documents

☐	eifu-multilingual.pdf	[TEST] Harborline Im...		...
☐	multi-eo-product-label.pdf	[TEST] Harborline Im...		...

Showing 2 unchanged documents [Hide](#)

Ready to release? Ready



Every upload has a section.
Settings / Review policy · Documents



Your organisation's country is not this device's market, so the release needs a confirmed authorised representative — appoint one under Who receives it, then confirm.
Who receives it · Release authority & reviewers · recommended — you can still release
MDIS compares your organisation's country (from its SRN) with this device's market. Your representative is appointed under Who receives it — a partner you are already connected to at once, a new one once they accept the invitation. Confirming records that the appointment covers this market.
[Confirm the appointment](#)
[Open Who receives it](#)

Capture SHA-256: 76876ad4ddd4bde0a82e58264f7c45f4e6fdcc5fb1c35a1cd46b2b25aa66e717

07

EXECUTED GHERKIN STEP

And I clear any carried blocking approvers PASS

 Technical file 

 TN [TEST] Northstar Medical Im...  EM
Manufacturer

Who receives it 

TH [TEST] Harborline Importers
Importer - all 2 documents - on delivery

TS [TEST] Sectra Distribution
Distributor - all 2 documents - on delivery

Approvals, in order 

At once  In order

EA E2E Authorised Rep Co
Authorised Representative

None Review Approve

TH [TEST] Harborline Importers
Importer

None Review Approve

TS [TEST] Sectra Distribution
Distributor

None Review Approve

EM E2E Manufacturer
In your organisation

None Review Approve

Capture SHA-256: 47a029fc684e8a4745c341101b4ab174547670f83731b6857e913ec9805d1ebd

08

EXECUTED GHERKIN STEP

And I complete and confirm the current release authority **PASS***No visible change at this step; release authority was already confirmed*

 Technical file 

  [TEST] Northstar Medical Im...
Manufacturer 

Who receives it

Choose who

TH

[TEST] Harborline Importers

Importer · all 2 documents · on delivery

TS

[TEST] Sectra Distribution

Distributor · all 2 documents · on delivery

Approvals, in order

At once

In order

EA

E2E Authorised Rep Co

Authorised Representative

None

Review

Approve

TH

[TEST] Harborline Importers

Importer

None

Review

Approve

TS

[TEST] Sectra Distribution

Distributor

None

Review

Approve

EM

E2E Manufacturer

In your organisation

None

Review

Approve

Capture SHA-256: 47a029fc684e8a4745c341101b4ab174547670f83731b6857e913ec9805d1ebd

09

EXECUTED GHERKIN STEP

And I configure the importer and the distributor as reviewers only PASS

 Technical file 

  [TEST] Northstar Medical Im...
Manufacturer  

Who receives it

Choose who

 [TEST] Harborline Importers

Importer - all 2 documents - on delivery

 [TEST] Sectra Distribution

Distributor - all 2 documents - on delivery

Approvals, in order

At once

In order

 [TEST] Harborline Importers

Importer - Reviewer

None

Review

Approve

 [TEST] Sectra Distribution

Distributor - Reviewer

None

Review

Approve

 E2E Authorised Rep Co

Authorised Representative

None

Review

Approve

 E2E Manufacturer

In your organisation

None

Review

Approve

Capture SHA-256: 9fd06181dd459cdfd18fec6a5d52d7c0a9dea98da927c6e50eaaa533a2f8a961

10

EXECUTED GHERKIN STEP

And I release this tracked candidate once PASS

 Technical file 

  [TEST] Northstar Medical Im...  

Home > AtlasView Multi-EO Release Monitor > Change 2

AM

Change 2 Draft

Version 1.3 importer and distributor as reviewers follows 1.2 PRRC as an ordered approver released 9 Sept [Rename](#)

 **Documents** 2

 Add files

 Drop PDFs here · section guessed from the filename, you confirm

 IFU & labelling

2 documents

☐	eifu-multilingual.pdf	[TEST] Harborline Im...		...
☐	multi-eo-product-label.pdf	[TEST] Harborline Im...		...

Showing 2 unchanged documents [Hide](#)

Ready to release? Ready



Every upload has a section.
Settings / Review policy · Documents



Your organisation's country is not this device's market, so the release needs a confirmed authorised representative — appoint one under Who receives it, then confirm.
Who receives it · Release authority & reviewers · recommended — you can still release
MDIS compares your organisation's country (from its SRN) with this device's market. Your representative is appointed under Who receives it — a partner you are already connected to at once, a new one once they accept the invitation. Confirming records that the appointment covers this market.
[Confirm the appointment](#)
[Open Who receives it](#)

Capture SHA-256: 4cdb9148a3adb18a30ccfb0704fff4d7620ba3565a5bfdf92b93071929b2da1c

11 EXECUTED GHERKIN STEP
Then the release is delivered immediately PASS

 Technical file 

 TN [TEST] Northstar Medical Im...  EM

Home > AtlasView Multi-EO Release Monitor > Change 2

AM

Change 2

Delivered

Version 1.3 importer and distributor as reviewers on the market since 9 Sept

 **Documents** 2 · frozen as released

 **IFU & labelling**

2 documents

eifu-multilingual.pdf	[TEST] Sectra Distrib...		...
multi-eo-product-label.pdf	[TEST] Harborline Im...		...

Showing 2 unchanged documents

Hide

 **Registration**

Incomplete

28 of 65 answers · EUDAMED XML needs all 65 · not needed to release

Answer remaining 37

Open registration

Who receives it

Choose who

TS **[TEST] Sectra Distribution**

Distributor · all 2 documents

TH **[TEST] Harborline Importers**

Importer · all 2 documents

Approvals, in order

1 **[TEST] Sectra Distribution**

Reviewer · Asked now

Now

Capture SHA-256: b0da280bae2a93a777e3224f9650686ad07b6f9a83f00919fc560e691e8d2dad

12

EXECUTED GHERKIN STEP

When I switch to the exact release-native importer PASS

 Technical file 

 [TEST] Harborline Importers  

Your work

[TEST] Harborline Importers · Wednesday 9 September

 **1** release to approve

 **8** devices shared with you

Needs you

 **AtlasView Multi-EO Release Monitor**
Approve the release · Review requested by [TEST] Northstar Medical Imaging

Approve

Devices · 8 

	AtlasView Importer Verifi...	Unreleased
	AtlasView Importer Rejec...	Unreleased
	AtlasView Distributor Veri...	Unreleased
	AtlasView Distributor Gu...	Unreleased
	ClearPath Release Monitor Candidate 1 released 9 Sept	Released
	AtlasView Multi-EO Release...	Released

Capture SHA-256: 3732ef8da95b5f75b7d17258512bb1fb620a049f3d6080e722fd07a74851d352

13

EXECUTED GHERKIN STEP

And I open the tracked approval for "AtlasView Multi-EO Release Monitor" from the work queue **PASS**

 Technical file   [TEST] Harborline Importers  

Your work › AtlasView Multi-EO Release Monitor › 1.3 importer and distributor as reviewers

AM **Approve the release** **Delivered**

[TEST] Northstar Medical Imaging · released 9 Sept · 2 documents · your approval is your verification of this release

Frozen release documents 2 documents

eifu-multilingual.pdf

multi-eo-product-label.pdf

PDF review **Exact revision**

Opening the signed PDF...

Start a feedback thread

Whole document

Page 1

Region

Describe what needs attention

Blocks approval

Note only

Blocking findings go to the manufacturer with "Request changes". Notes travel with either decision and never hold anything.

Open thread

Capture SHA-256: e5a075b2ba2372e7714ddb94aa2436096c183d1ecfd9d638eb7d7d2bddf4e442

14

EXECUTED GHERKIN STEP

Then I can open exactly the release's frozen documents **PASS**

 Technical file 

  [TEST] Harborline Importers  

Your work > AtlasView Multi-EO Release Monitor > 1.3 importer and distributor as reviewers

AM

Approve the release Delivered

[TEST] Northstar Medical Imaging · released 9 Sept · 2 documents · your approval is your verification of this release

Frozen release documents

2 documents

eifu-multilingual.pdf

multi-eo-product-label.pdf

PDF review

Exact revision

Download

E2E multilingual IFU - English / Nederlands

Capture SHA-256: 3993de62ace2fb61dcd9b88a27514f49860be29243dbc64473e9d35d2f368615

15

EXECUTED GHERKIN STEP

When I approve the tracked release **PASS**

 Technical file ▼

 TH [TEST] Harborline Importers ▼ EI

Start a feedback thread

Whole document

Page 1

Region

Describe what needs attention

Blocks approval

Note only

Blocking findings go to the manufacturer with "Request changes". Notes travel with either decision and never hold anything.

Open thread

Your decision

Reviewer · [TEST] Harborline Importers

✓ Approve

↶ Request changes

Your review is recorded on the release; it holds nothing.

Signed outside MDIS? optional

Reference, e.g. DocuSign envelope id

If your organisation signs its verification elsewhere, the reference is kept with this approval.

Recording...

Capture SHA-256: cfd628e40fca8c4bf4d6b058270b23febbaa8c50a437fa5744ad8312ca70ad7b

MDIS walkthrough · 77 / 418

16

EXECUTED GHERKIN STEP

Then the approval decision is durably recorded **PASS**

The screenshot shows the MedQAIR interface. The top navigation bar includes the MedQAIR logo, a 'Technical file' dropdown, a refresh icon, a user profile for '[TEST] Harborline Importers' with a dropdown arrow, and a blue circular button with 'EI'. Below the navigation bar, the breadcrumb trail reads 'Your work > AtlasView Multi-EO Release Monitor > 1.3 importer and distributor as reviewers'. The main heading is 'Approve the release' with a green 'Delivered' status tag. Below the heading, it says '[TEST] Northstar Medical Imaging · released 9 Sept · 2 documents · your approval is your verification of this release'. A white message box contains the text 'Decision recorded.' followed by 'You approved this release. If you were the last approver, delivery has started by itself.' and a blue button labeled 'Back to your work'.

Capture SHA-256: 70d06848eb86a69006aa9a2ee4c4c885dfec61b14716bc2d47edbe07588d0b5e

17

EXECUTED GHERKIN STEP

When I switch to the exact release-native distributor PASS

MedQAIR Technical file [TEST] Sectra Distribution Distributor ED

Your work

[TEST] Sectra Distribution · Wednesday 9 September

+ Add a device

✓ 1 release to approve

4 devices shared with you

Needs you

AM

AtlasView Multi-EO Release Monitor
Approve the release · Review requested by [TEST] Northstar Medical Imaging

Approve

Devices · 4

All 4 >

Q Name, UDI-DI or Basic UDI-DI

AD	AtlasView Distributor Veri...	Unreleased
AD	AtlasView Distributor Gu...	Unreleased
AM	AtlasView Multi-EO Release... 1.2 PRRC as an ordered approve...	Released
ER	E2E Release Ledger Synthe... 1.0 released 9 Sept	Released

Capture SHA-256: dd709f6c68bc8f28c6a3c248718f04e71e1e1a4cdd444d2e90df6c7d55a97ab4

18

EXECUTED GHERKIN STEP

And I open the tracked approval for "AtlasView Multi-EO Release Monitor" from the work queue PASS

 Technical file [TEST] Sectra Distribution Distributor ED

Your work › AtlasView Multi-EO Release Monitor › 1.3 importer and distributor as reviewers

AM **Approve the release** Delivered

[TEST] Northstar Medical Imaging · released 9 Sept · 2 documents · your approval is your verification of this release

Frozen release documents 2 documents

eifu-multilingual.pdf

multi-eo-product-label.pdf

PDF review Exact revision

E2E multilingual IFU - English / Nederlands

Download

Capture SHA-256: 7354100a0b02a17ba321bec7fd95f164c55c34a25cf2c01fe50f42dadd3a804

19

EXECUTED GHERKIN STEP

When I request changes on the tracked release as an advisory reviewer PASS

 Technical file [TEST] Sectra Distribution Distributor ED

Your work › AtlasView Multi-EO Release Monitor › 1.3 importer and distributor as reviewers

AM

Approve the release

Delivered

[TEST] Northstar Medical Imaging · released 9 Sept · 2 documents · your approval is your verification of this release

Decision recorded.

You requested changes. Delivery stopped; the manufacturer sees your findings at the top of their change page.

[Back to your work](#)

Capture SHA-256: 5a099278206f791470bc2308e435a54afbb8f5c50682a02ea3fe6c308a0520c5

20

EXECUTED GHERKIN STEP

Then the approval decision is durably recorded **PASS**

No visible change at this step; the recorded approval decision remains visibly shown

 **Technical file** 

  **[TEST] Sectra Distribution**  

Your work › AtlasView Multi-EO Release Monitor › 1.3 importer and distributor as reviewers

 **Approve the release** 

[TEST] Northstar Medical Imaging · released 9 Sept · 2 documents · your approval is your verification of this release

Decision recorded.

You requested changes. Delivery stopped; the manufacturer sees your findings at the top of their change page.

[Back to your work](#)

Capture SHA-256: 5a099278206f791470bc2308e435a54afbb8f5c50682a02ea3fe6c308a0520c5

21

EXECUTED GHERKIN STEP

When I switch back to the manufacturer **PASS**

 Technical file 

 **TN** [TEST] Northstar Medical Im...
Manufacturer  **EM**

Your work

[TEST] Northstar Medical Imaging · Wednesday 9 September

 **12**
drafts to finish

 **0**
returned for changes

 **0**
waiting on a partner

 **41**
devices, 6 released

 Add a device

Needs you

12 drafts

NV

Northstar VitalSync Patient Monitor
1.1 labelling update

Continue

NS

Northstar SonoLite Handheld Ultrasound
1.0 first release

Continue

NC

Northstar CardioMesh Coronary Stent
1.0 first release

Continue

NL

Northstar LumaDerm Phototherapy Lamp
Change 1 · first release

Continue



E2E Journey Device 1788933641806128
Change 1 · 1.0.0 · first release

Continue



E2E Journey Device 1788933703671839
Change 1 · 1.0.0 · first release

Continue

Devices · 41

[All 41 >](#)

PA

PulseView AR Validation ...

Unreleased

AP

AtlasView PRRC Validatio...

Unreleased

AA

AtlasView AR Verification ...

Unreleased

AA

AtlasView AR Validation ...

Unreleased

AI

AtlasView Importer Verifi...

Unreleased

AI

AtlasView Importer Rejec...

Unreleased

Capture SHA-256: 2635fc1c93d52d0a66885acc0e57e65bb091a15eb467f6eff4e140170fab9ef9

22

EXECUTED GHERKIN STEP

And I reopen the tracked release PASS

 **Technical file** 

  **[TEST] Northstar Medical Im...**  

Home > AtlasView Multi-EO Release Monitor > Change 2

Delivered to the frozen recipient set

AM

Change 2 Delivered

Version 1.3 importer and distributor as reviewers on the market since 9 Sept · returned 9 Sept by [TEST] Sectra Distribution

 **Documents** 2 · frozen as released

Find

2 unchanged documents

Show all

 **Registration** Incomplete

28 of 65 answers · EUDAMED XML needs all 65 · not needed to release

Answer remaining 37

Open registration

Who receives it Choose who

 **[TEST] Sectra Distribution**
Distributor · all 2 documents

 **[TEST] Harborline Importers**
Importer · all 2 documents

Approvals, in order

 **[TEST] Sectra Distribution**
Reviewer · Requested changes 9 Sept

Capture SHA-256: 6911f2f8a59255e0a1d57abd7c1f9a6a5e292abc66c89c510791788c51d4512b

MDIS walkthrough · 84 / 418

23

EXECUTED GHERKIN STEP

Then the tracked release is still delivered **PASS**

No visible change at this step; the delivered action bar remains visibly shown

 **Technical file** 

  **[TEST] Northstar Medical Im...**  

Home › AtlasView Multi-EO Release Monitor › Change 2

Delivered to the frozen recipient set

AM

Change 2 **Delivered**

Version 1.3 importer and distributor as reviewers on the market since 9 Sept · returned 9 Sept by [TEST] Sectra Distribution

 **Documents** 2 · frozen as released

Find

2 unchanged documents

Show all

 **Registration** **Incomplete**

28 of 65 answers · EUDAMED XML needs all 65 · not needed to release

Answer remaining 37

Open registration

Who receives it Choose who

 **[TEST] Sectra Distribution**
Distributor · all 2 documents

 **[TEST] Harborline Importers**
Importer · all 2 documents

Approvals, in order

 **[TEST] Sectra Distribution**
Reviewer · Requested changes 9 Sept

Capture SHA-256: 6911f2f8a59255e0a1d57abd7c1f9a6a5e292abc66c89c510791788c51d4512b

24

EXECUTED GHERKIN STEP

And the recorded chain shows the importer approved and the distributor requested changes, holding nothing PASS*No visible change at this step; asserted through the API read*

 **Technical file** 

  **[TEST] Northstar Medical Im...**  

Home › AtlasView Multi-EO Release Monitor › Change 2

Delivered to the frozen recipient set

AM

Change 2

Delivered

Version 1.3 importer and distributor as reviewers on the market since 9 Sept · returned 9 Sept by [TEST] Sectra Distribution

 **Documents** 2 · frozen as released

Find

2 unchanged documents [Show all](#)

 **Registration** Incomplete

28 of 65 answers · EUDAMED XML needs all 65 · not needed to release

Answer remaining 37

Open registration

Who receives it Choose who

 **[TEST] Sectra Distribution**
Distributor · all 2 documents

 **[TEST] Harborline Importers**
Importer · all 2 documents

Approvals, in order

 **[TEST] Sectra Distribution**
Reviewer · Requested changes 9 Sept

Capture SHA-256: 6911f2f8a59255e0a1d57abd7c1f9a6a5e292abc66c89c510791788c51d4512b

A visible changes request stops one release and its successor can deliver

Starting condition: this correction story uses a device that already carries releases from sibling scenarios in the run.

Correction event record

The sealed API sidecar resolves each event to the named person role and revision shown here. Identifiers remain in the evidence index.

Sequence	Event	Actor role	Revision	Revision label
1	opened	Authorised representative (reviewer)	multi-eo-product-label.pdf	No revision label recorded
2	closed_unresolved	Authorised representative (reviewer)	multi-eo-product-label.pdf	No revision label recorded
3	reopened	Authorised representative (reviewer)	multi-eo-product-label.pdf	No revision label recorded
4	comment_added	Manufacturer	multi-eo-product-label.pdf	No revision label recorded
5	addressed	Manufacturer	multi-eo-product-label.pdf	No revision label recorded
6	carried	Manufacturer	multi-eo-product-label.pdf	VAL-REL-019 corrected d9e0d654
7	resolved	Authorised representative (reviewer)	multi-eo-product-label.pdf	VAL-REL-019 corrected d9e0d654

01

EXECUTED GHERKIN STEP

Given the anchored-feedback participants use separate signed-in sessions PASS

 Technical file ⌵

   [TEST] Northstar Medical Im... ⌵ 

Manufacturer

Your work

[TEST] Northstar Medical Imaging · Wednesday 9 September

 **12**
drafts to finish

 **0**
returned for changes

 **0**
waiting on a partner

 **43**
devices, 8 released

+ Add a device

Needs you

12 drafts

	Northstar SonoLite Handheld Ultrasound 1.0 first release	Continue
	Northstar VitalSync Patient Monitor 1.1 labelling update	Continue
	Northstar CardioMesh Coronary Stent 1.0 first release	Continue
	Northstar LumaDerm Phototherapy Lamp Change 1 · first release	Continue
	E2E Journey Device 1788933641806128 Change 1 · 1.0.0 · first release	Continue
	E2E Journey Device 1788933703671839 Change 1 · 1.0.0 · first release	Continue

Devices · 43

All 43 >

	PulseView AR Validation ...	Unreleased
	AtlasView AR Verification ...	Unreleased
	AtlasView AR Validation ...	Unreleased
	AtlasView Importer Verifi...	Unreleased
	AtlasView Importer Rejec...	Unreleased
	AtlasView Distributor Veri...	Unreleased

Capture SHA-256: 8095590cd5022eed9d36c1316220d814f7fa52aa347767b791a6e897e2d9193

MDIS walkthrough · 88 / 418

02

EXECUTED GHERKIN STEP

And I open the current multi-EO release device PASS

 Technical file 

 TN [TEST] Northstar Medical Im...  EM

Home > Devices > AtlasView Multi-EO Release Monitor

AM **AtlasView Multi-EO Release Monitor** Released
current 1.3 importer and distributor as reviewers released 9 Sept - Basic UDI-DI 0950600090035B

Choose who [+ Start a change](#)

Changes and releases

Release history

✓ 1.3 importer and distributor as reviewers
Released 9 Sept - Change 2

Delivered Open

✓ 1.2 PRRC as an ordered approver
Released 9 Sept - Change 1

Delivered Open

Current file 1.3 importer and distributor as reviewers - 2 documents

Find

 **IFU & labelling** 2 documents

ifu-multilingual.pdf

multi-eo-product-label.pdf

Registration Open

28 of 65 answers - EUDAMED XML needs all 65

Who can open it Choose who

EA **E2E Authorised Rep Co**
Nothing yet - Authorised representative

TH **[TEST] Harborline Importers**
All documents

TS **[TEST] Sectra Distribution**
All documents

TS **[TEST] Sectra Distribution**
Nothing yet - Distributor - since 2100

TH **[TEST] Harborline Importers**
Nothing yet - Importer - since 2019

Capture SHA-256: 8506c3636974cb1fe55b78d205a62cbe7d1b0947594009a3d48069a9f8d6d3a2

03

EXECUTED GHERKIN STEP

And I open the device's access page **PASS**

 Technical file 

  [TEST] Northstar Medical Im...  

Home > AtlasView Multi-EO Release Monitor > Who receives it

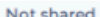
 **Who receives it**
Who can open AtlasView Multi-EO Release Monitor's documents.

Current access

Open Access from a draft change to choose the exact documents each partner will receive. Existing released access is shown here for reference.

IFU & labelling2 documents

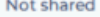
What each partner gets

 **E2E Authorised Rep Co**
Authorised representati... 

 **[TEST] Harborline I...**
Importer · since 2020 · ... 

 **[TEST] Sectra Distri...**
Distributor · since 202... 

 **[TEST] Sectra Distribu...**
Distributor · since 2100 

 **[TEST] Harborline Im...**
Importer · since 2019 

Choose a company... 

+ Add to this device

Invite a new company

Adding a company does not share anything

Capture SHA-256: b5119f4b66583544da9dc6ba2201322a0b462c5860d50b3a5b2b1db13d9aa7b1

04

EXECUTED GHERKIN STEP

And I add the authorised representative to this device PASS

No visible change at this step; the authorised representative was already connected to this device

 **Technical file** 

 TN **[TEST] Northstar Medical Im...**  EM

Home > AtlasView Multi-EO Release Monitor > Who receives it

AM

Who receives it
Who can open AtlasView Multi-EO Release Monitor's documents.

Current access

Open Access from a draft change to choose the exact documents each partner will receive. Existing released access is shown here for reference.

IFU & labelling

2 documents

What each partner gets

EA **E2E Authorised Rep Co**
Authorised representati... Not shared

TH **[TEST] Harborline I...**
Importer · since 2020 · ... 2 documents

TS **[TEST] Sectra Distri...**
Distributor · since 202... 2 documents

TS **[TEST] Sectra Distribu...**
Distributor · since 2100 Not shared

TH **[TEST] Harborline Im...**
Importer · since 2019 Not shared

Choose a company... 

+ Add to this device

Invite a new company

Adding a company does not share anything

Capture SHA-256: b5119f4b66583544da9dc6ba2201322a0b462c5860d50b3a5b2b1db13d9aa7b1

MDIS walkthrough · 91 / 418

05

EXECUTED GHERKIN STEP

And I go back to the device PASS

 Technical file 

 TN [TEST] Northstar Medical Im...  EM

Home > Devices > AtlasView Multi-EO Release Monitor

AM

AtlasView Multi-EO Release Monitor Released

current 1.3 importer and distributor as reviewers released 9 Sept · Basic UDI-DI 0950600090035B

Choose who

+ Start a change

Changes and releases

Release history

✓ 1.3 importer and distributor as reviewers
Released 9 Sept · Change 2

Delivered Open

✓ 1.2 PRRC as an ordered approver
Released 9 Sept · Change 1

Delivered Open

Current file 1.3 importer and distributor as reviewers · 2 documents

Find

 IFU & labelling 2 documents

eifu-multilingual.pdf

multi-eo-product-label.pdf

Registration

Open

28 of 65 answers · EUDAMED XML needs all 65

Who can open it

Choose who

EA **E2E Authorised Rep Co**
Nothing yet · Authorised representative

TH **[TEST] Harborline Importers**
All documents

TS **[TEST] Sectra Distribution**
All documents

TS **[TEST] Sectra Distribution**
Nothing yet · Distributor · since 2100

TH **[TEST] Harborline Importers**
Nothing yet · Importer · since 2019

Capture SHA-256: 9ff8c85af0aefd1cdb834b124f766dbab270cd22bbb682a5330d77f6ab65ca83

06

EXECUTED GHERKIN STEP

And I start production version "VAL-REL-019 automated review" PASS

 Technical file 

  [TEST] Northstar Medical Im...  

Home > AtlasView Multi-EO Release Monitor > Change 3

 **Change 3** Draft

Version VAL-REL-019 automated review follows 1.3 importer and distributor as reviewers released 9 Sept [Rename](#)

 **Documents** 2

 Add files

 Drop PDFs here · section guessed from the filename, you confirm

2 unchanged documents [Show all](#)

Ready to release? Ready

 **Every upload has a section.**
Settings / Review policy · Documents

 **Your organisation's country is not this device's market, so the release needs a confirmed authorised representative — appoint one under Who receives it, then confirm.**
Who receives it · Release authority & reviewers · recommended — you can still release
MDIS compares your organisation's country (from its SRN) with this device's market. Your representative is appointed under Who receives it — a partner you are already connected to at once, a new one once they accept the invitation. Confirming records that the appointment covers this market.
[Confirm the appointment](#)
[Open Who receives it](#)

Capture SHA-256: ea7433ec336a5369fa6a2a3819287deca2ec5e4f62084c45475c6726c0967689

07

EXECUTED GHERKIN STEP

And I ensure the current release has two documents PASS

 Technical file 

  [TEST] Northstar Medical Im...  

Home > AtlasView Multi-EO Release Monitor > Change 3

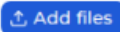
AM

Change 3

Draft

Version VAL-REL-019 automated review follows 1.3 importer and distributor as reviewers released 9 Sept [Rename](#)

 Documents 2

Find 

 Drop PDFs here · section guessed from the filename, you confirm

 IFU & labelling

2 documents

☐

eifu-multilingual.pdf

[TEST] Harborline Im...



...

☐

multi-eo-product-label.pdf

[TEST] Harborline Im...



...

Showing 2 unchanged documents [Hide](#)

Ready to release?

Ready



Every upload has a section.

Settings / Review policy · Documents



Your organisation's country is not this device's market, so the release needs a confirmed authorised representative — appoint one under Who receives it, then confirm.

Who receives it · Release authority & reviewers · recommended — you can still release

MDIS compares your organisation's country (from its SRN) with this device's market. Your representative is appointed under Who receives it — a partner you are already connected to at once, a new one once they accept the invitation. Confirming records that the appointment covers this market.

[Confirm the appointment](#)

[Open Who receives it](#)

Capture SHA-256: d273423b330a05e2f67c8a0c367861eea7bcccc8594306c7f76df0bfdd91437a

08

EXECUTED GHERKIN STEP

And I complete and confirm the current release authority PASS

No visible change at this step; release authority was already confirmed

 **Technical file** 

 **TN** [TEST] Northstar Medical Im...  **EM**

Home > AtlasView Multi-EO Release Monitor > Change 3

Change 3 Draft

Version VAL-REL-019 automated review follows 1.3 importer and distributor as reviewers released 9 Sept [Rename](#)

 **Documents** 2 [Add files](#)

 **Drop PDFs here** · section guessed from the filename, you confirm

 **IFU & labelling** 2 documents

☐	eifu-multilingual.pdf	[TEST] Harborline Im...		...
☐	multi-eo-product-label.pdf	[TEST] Harborline Im...		...

Showing 2 unchanged documents [Hide](#)

Ready to release? Ready

 **Every upload has a section.**
Settings / Review policy · Documents

 **Your organisation's country is not this device's market, so the release needs a confirmed authorised representative — appoint one under Who receives it, then confirm.**
Who receives it · Release authority & reviewers · recommended — you can still release
MDIS compares your organisation's country (from its SRN) with this device's market. Your representative is appointed under Who receives it — a partner you are already connected to at once, a new one once they accept the invitation. Confirming records that the appointment covers this market.
[Confirm the appointment](#)
[Open Who receives it](#)

Capture SHA-256: d273423b330a05e2f67c8a0c367861eea7bcccc8594306c7f76df0bfdd91437a

09

EXECUTED GHERKIN STEP

And I configure the fresh anchored-feedback delivery **PASS**

 Technical file 

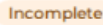
  **[TEST] Northstar Medical Im...**  

Who receives it, then confirm.
Who receives it · Release authority & reviewers · recommended — you can still release

MDIS compares your organisation's country (from its SRN) with this device's market. Your representative is appointed under Who receives it — a partner you are already connected to at once, a new one once they accept the invitation. Confirming records that the appointment covers this market.

[Confirm the appointment](#)

[Open Who receives it](#)

 **Registration** 

28 of 65 answers · EUDAMED XML needs all 65 · not needed to release

[Answer remaining 37](#)

[Open registration](#)

Who receives it [Choose who](#)

 **[TEST] Harborline Importers**
Importer · IFU & labelling · 1 document · ...

Capture SHA-256: c123f69d975aa09b472b45bd4309c19c93321117cb3fa193e2a6638198abc259

10

EXECUTED GHERKIN STEP

And I configure the authorised representative as a blocking approver PASS

MedQAIR Technical file

[TEST] Northstar Medical Im... Manufacturer

Approvals, in order **At once** In order

EA	E2E Authorised Rep Co Authorised Representative - Approver	None	Review	Approve
TH	[TEST] Harborline Importers Importer - Reviewer	None	Review	Approve
TS	[TEST] Sectra Distribution Distributor - Reviewer	None	Review	Approve
EM	E2E Manufacturer In your organisation	None	Review	Approve
EP	E2E PRRC In your organisation - PRRC	None	Review	Approve
EE	E2E eIFU Reader In your organisation	None	Review	Approve

Capture SHA-256: e8209884a4f09f8940835cfd3f795b427107527986c21e299813f91528c442fe

11

EXECUTED GHERKIN STEP

And I release this tracked candidate once PASS

 Technical file 

 TN [TEST] Northstar Medical Im...  EM

Home > AtlasView Multi-EO Release Monitor > Change 3

AM **Change 3** Draft

Version VAL-REL-019 automated review follows 1.3 importer and distributor as reviewers released 9 Sept Rename

 **Documents** 2 Add files

 **Drop PDFs here** · section guessed from the filename, you confirm

2 unchanged documents Show all

Ready to release? Ready

 **Every upload has a section.**
Settings / Review policy · Documents

 **Your organisation's country is not this device's market, so the release needs a confirmed authorised representative — appoint one under Who receives it, then confirm.**
Who receives it · Release authority & reviewers · recommended — you can still release
MDIS compares your organisation's country (from its SRN) with this device's market. Your representative is appointed under Who receives it — a partner you are already connected to at once, a new one once they accept the invitation. Confirming records that the appointment covers this market.
Confirm the appointment
[Open Who receives it](#)

Capture SHA-256: b9cc4d43dd51cf98bf1ea08985144d485885d952830bbcf4fddc26004686f625

12

EXECUTED GHERKIN STEP

Then delivery is visibly waiting for its blocking decision PASS

 **Technical file** 

  **[TEST] Northstar Medical Im...** 
Manufacturer 

Home › AtlasView Multi-EO Release Monitor › Change 3

AM **Change 3** Waiting

Version VAL-REL-019 automated review follows 1.3 importer and distributor as reviewers released 9 Sept

 **Documents** 2 · frozen as released

2 unchanged documents [Show all](#)

 **Registration** Incomplete

28 of 65 answers · EUDAMED XML needs all 65 · not needed to release

Answer remaining 37

Open registration

Who receives it Choose who

 **[TEST] Harborline Importers**
Importer · IFU & labelling · 1 document · ...

Approvals, in order

1 **[TEST] Harborline Importers** Now

Reviewer · Asked now

2 **[TEST] Sectra Distribution** Now

Reviewer · Asked now

Capture SHA-256: 3e7d3125ccf1135c3c7800437c3f809df3357ff679945a43aec77eec179abc6b

13

EXECUTED GHERKIN STEP

When the authorised representative takes over the anchored-feedback review PASS

 Technical file 

  EA E2E Authorised Rep Co
Authorised Representative  EA

Your work

E2E Authorised Rep Co · Wednesday 9 September

 **2**
releases to approve

 **10**
devices shared with you

Needs you

NN**Northstar NeuroScan EEG Cap**
Approve the release · Review requested by [TEST] Northstar Medical Imaging

Approve

NO**Northstar OxyTrack Pulse Oximeter**
Approve the release · Approval requested by [TEST] Northstar Medical Imaging

Approve

Devices · 10[All 10 >](#)

PA**PulseView AR Validation ...**Unreleased

AA**AtlasView AR Verification ...**Unreleased

AA**AtlasView AR Validation ...**Unreleased

CR**ClearPath Release Monitor**
Candidate 1 released 9 Sept

Released

AM**AtlasView Multi-EO Release...**
1.2 PRRC as an ordered approve...

Released

EA**E2E Release Ledger Synthe...**

Released

Capture SHA-256: c2f12ebb33a1e09c713f24718d4145526dd1340b4349ceab578f16881eceeac

14

EXECUTED GHERKIN STEP

And I open the exact anchored-feedback approval from the work queue **PASS**

MedQAIR Technical file ↻ EA E2E Authorised Rep Co Authorised Representative EA

Your work > AtlasView Multi-EO Release Monitor > VAL-REL-019 automated review

AM Approve the release Waiting

[TEST] Northstar Medical Imaging · released 9 Sept · 2 documents · your approval holds delivery · it starts by itself after the last one

Frozen release documents 2 documents

eifu-multilingual.pdf multi-eo-product-label.pdf

PDF review Exact revision Download

E2E multilingual IFU - English / Nederlands

Capture SHA-256: 730cba98a89e61e525c07ab70bf2dd4eca39337601d23b54457bbf554d4a36a4

15

EXECUTED GHERKIN STEP

And I open anchored feedback on the changed and unaffected PDFs **PASS**

 Technical file 

 EA E2E Authorised Rep Co
Authorised Representative EA

Start a feedback thread

Whole document Page 1 Region

Describe what needs attention

Blocks approval Note only

Blocking findings go to the manufacturer with "Request changes". Notes travel with either decision and never hold anything.

Open thread

Findings on this document 1 blocking

Confirm the unchanged instructions page remains legible.

Open Blocking

reviewer

Confirm the unchanged instructions page remains legible.

Reply

Resolve Close unresolved

Capture SHA-256: 8fed7da945f389b834045e35c905ce7e9fb423217d4849d6bd3a1abe658ff726

16

EXECUTED GHERKIN STEP

When I close the anchored finding as unresolved **PASS**

 Technical file 

  E2E Authorised Rep Co
Authorised Representative  

Open thread

Findings on this document 1 blocking

Move the highlighted product label away from the fold line.

Closed

Blocking

reviewer

Move the highlighted product label away from the fold line.

Reply

Reopen

Your decision

Approver · E2E Authorised Rep Co

Your approval is your Article 11 verification of this release.

✓ Approve

↶ Request changes

Record decision

Capture SHA-256: 846371e4c15a9a7e9f51b7e08eac6fcdeb0963273cae7e342c8b6950f9abceaa

17

EXECUTED GHERKIN STEP

And I reopen the anchored finding and verify the recorded actions **PASS**

Evidence note: Reopen returns the finding to Open; the API retains the reviewer's closed_unresolved and reopened events. Step 22 shows the manufacturer's reply and Addressed state; step 38 verifies the sealed record through API reads.

 Technical file 

 EA E2E Authorised Rep Co
Authorised Representative  EA

Open thread

Findings on this document 1 blocking

Move the highlighted product label away from the fold line.

Open Blocking

reviewer

Move the highlighted product label away from the fold line.

Reply

Resolve Close unresolved

Your decision Approver - E2E Authorised Rep Co

Your approval is your Article 11 verification of this release.

✓ Approve Request changes

Record decision

Capture SHA-256: c196778fd9d52f1eea5602e05cfcc4af303441182a5b74485fb7ee9c93e753db

18

EXECUTED GHERKIN STEP

When I request the anchored correction on the frozen release PASS

 Technical file ↕

↻ EA E2E Authorised Rep Co Authorised Representative ↕ EA

Your work › AtlasView Multi-EO Release Monitor › VAL-REL-019 automated review

AM **Approve the release** Returned

[TEST] Northstar Medical Imaging · released 9 Sept · 2 documents · you requested changes · not delivered

Decision recorded.

You requested changes. Delivery stopped; the manufacturer sees your findings at the top of their change page.

[Back to your work](#)

Capture SHA-256: 72b7334962fa2856e14d07749368f122ddeb93f81f96cbaa717e999a034ea11a

19

EXECUTED GHERKIN STEP

Then the anchored-feedback approval decision is durably recorded **PASS**

No visible change at this step; the terminal Decision recorded card was already visible after the decision action

 **Technical file** 

 **EA** **E2E Authorised Rep Co**  **EA**
Authorised Representative

Your work > AtlasView Multi-EO Release Monitor > VAL-REL-019 automated review

AM **Approve the release** **Returned**

[TEST] Northstar Medical Imaging · released 9 Sept · 2 documents · you requested changes · not delivered

Decision recorded.

You requested changes. Delivery stopped; the manufacturer sees your findings at the top of their change page.

[Back to your work](#)

Capture SHA-256: 72b7334962fa2856e14d07749368f122ddeb93f81f96cbaa717e999a034ea11a

20

EXECUTED GHERKIN STEP

When the Manufacturer resumes the anchored-feedback release **PASS**

 **Technical file** 

 **TN** **[TEST] Northstar Medical Im...**  **EM**

Home › AtlasView Multi-EO Release Monitor › Change 3

Waiting for approval **Withdraw release**

AM **Change 3** **Waiting**

Version VAL-REL-019 automated review follows VAL-REL-019 automated review released 9 Sept

 **Documents** 2 · frozen as released

2 unchanged documents [Show all](#)

 **Registration** **Incomplete**

28 of 65 answers · EUDAMED XML needs all 65 · not needed to release

Answer remaining 37

Open registration

Who receives it Choose who

 **[TEST] Harborline Importers**

Importer · IFU & labelling · 1 document · ...

Approvals, in order

1 **[TEST] Harborline Importers** **Now**

Reviewer · Asked now

2 **[TEST] Sectra Distribution** **Now**

Reviewer · Asked now

Capture SHA-256: 4acf0e8f72907d4730a7a4c398dcb4ec8967f85f584748ce00f3c07795c0d722

21

EXECUTED GHERKIN STEP

And I reopen the tracked release **PASS**

 **Technical file** 

  **[TEST] Northstar Medical Im...**  

Home > AtlasView Multi-EO Release Monitor > Change 3

AM **Change 3** **Returned**

Version VAL-REL-019 automated review follows VAL-REL-019 automated review released 9 Sept - returned 9 Sept by E2E Authorised Rep Co

Returned with findings; fix them in the next release **Start the next release** **Withdraw release**

 **Changes requested** **2 unresolved** **Open feedback view**

eifu-multilingual.pdf:
"Confirm the unchanged instructions page remains legible."

multi-eo-product-label.pdf:
"Move the highlighted product label away from the fold line."

 **Documents** **2** · frozen as released **Find**

2 unchanged documents **Show all**

 **Registration** **Incomplete**

28 of 65 answers · EUDAMED XML needs all 65 · not needed to release

Answer remaining 37

Open registration

Who receives it **Choose who**

 **[TEST] Harborline Importers**
Importer · IFU & labelling · 1 document · ...

Approvals, in order

1 **[TEST] Harborline Importers** **Now**
Reviewer · Asked now

[TEST] Harborline Importers

Capture SHA-256: e522eaff700bb26ebbe6c031b2da5fc223ad2565d16d4915969d12d91bf48e52

22

EXECUTED GHERKIN STEP

Then the Manufacturer discovers and answers the anchored feedback PASS

MedQAIR Technical file

Findings, at the spot they were raised

eifu-multilingual.pdf multi-eo-product-label.pdf

PDF review Exact revision Download

Multi-EO Product Label

Findings on this document 1 blocking

Move the highlighted product label away from the fold line.

Addressed Blocking

reviewer
Move the highlighted product label away from the fold line.

manufacturer
Corrected label proof prepared; the instructions remain unchanged.

Decisions are your reviewer's — the threads are yours to answer.

eifu-multilingual.pdf rev 1 Awaiting decision

multi-eo-product-label.pdf rev 1 Awaiting decision

Verification record

builds as decisions land · sealed at release

Export

multi-eo-product-label.pdf
Closed unresolved — disagreement recorded · 2026-09-09

multi-eo-product-label.pdf
Reopened by reviewer · 2026-09-09

Capture SHA-256: 349e90478ffd58470c0e2b42f7f34785e3a8750b769a47b8f9b2660be3476ba2

23

EXECUTED GHERKIN STEP

When I start the supported further-release remedy PASS

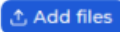
 Technical file 

  [TEST] Northstar Medical Im...  

Home > AtlasView Multi-EO Release Monitor > Change 4

 **Change 4** Draft
follows VAL-REL-019 automated review released 9 Sept

 Documents 2

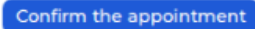
Find 

 Drop PDFs here · section guessed from the filename, you confirm

2 unchanged documents [Show all](#)

Ready to release? Ready

 **Every upload has a section.**
Settings / Review policy · Documents

 **Your organisation's country is not this device's market, so the release needs a confirmed authorised representative — appoint one under Who receives it, then confirm.**
Who receives it · Release authority & reviewers · recommended — you can still release
MDIS compares your organisation's country (from its SRN) with this device's market. Your representative is appointed under Who receives it — a partner you are already connected to at once, a new one once they accept the invitation. Confirming records that the appointment covers this market.

[Open Who receives it](#)

Capture SHA-256: b220c87592228c89cf4d7cc3c75c77cb38a70a0287a68df14a9179d0c8358e9f

24

EXECUTED GHERKIN STEP

Then the successor keeps its approver editable and shows its saved audience counts PASS

No visible change at this step; the successor's approver controls and saved audience counts remain visible after the round trip

 Technical file 

 TN [TEST] Northstar Medical Im...  EM

Home > AtlasView Multi-EO Release Monitor > Change 4

AM **Change 4** Draft

follows VAL-REL-019 automated review released 9 Sept

 Documents 2

Find

 Add files

 Drop PDFs here · section guessed from the filename, you confirm

2 unchanged documents

Show all

Ready to release? Ready

 Every upload has a section.
Settings / Review policy · Documents

 Your organisation's country is not this device's market, so the release needs a confirmed authorised representative — appoint one under Who receives it, then confirm.
Who receives it · Release authority & reviewers · recommended — you can still release
MDIS compares your organisation's country (from its SRN) with this device's market. Your representative is appointed under Who receives it — a partner you are already connected to at once, a new one once they accept the invitation. Confirming records that the appointment covers this market.
Confirm the appointment
[Open Who receives it](#)

Capture SHA-256: b220c87592228c89cf4d7cc3c75c77cb38a70a0287a68df14a9179d0c8358e9f

25

EXECUTED GHERKIN STEP

When I upload the corrected immutable successor revision PASS

 Technical file ↕

⌚ TN [TEST] Northstar Medical Im... ↕ EM
Manufacturer

Home › AtlasView Multi-EO Release Monitor › Change 4

AM **Change 4** Draft
follows VAL-REL-019 automated review released 9 Sept

📄 **Documents** 2 · 1 changed Find ⬆️ Add files

⬆️ **Drop PDFs here** · section guessed from the filename, you confirm

📄 **IFU & labelling** 2 documents

☐ **multi-eo-product-label.pdf**
Replaces previous

VAL -
REL - 019
corrected
d9e0d654

👁 ...

☐ **eifu-multilingual.pdf**

👁 ...

Showing 1 unchanged documents Hide

Ready to release? Ready

✓ **Every upload has a section.**
Settings / Review policy · Documents

⚠️ **Your organisation's country is not this device's market, so the release needs a confirmed authorised representative — appoint one under Who receives it, then confirm.**
Who receives it · Release authority & reviewers · recommended — you can still release
MDIS compares your organisation's country (from its SRN) with this device's market. Your representative is appointed under Who receives it — a partner you are already connected to at once, a new one once they accept the invitation. Confirming records that the appointment covers this market.
Confirm the appointment
[Open Who receives it](#)

Capture SHA-256: 8e9d6c456d95191183ca28020c367893138c484fab3b451768f67f6cd8197402

26

EXECUTED GHERKIN STEP

And I keep the corrected revision in the configured delivery **PASS**

 **Technical file** 

  **[TEST] Northstar Medical Im...**  

Home > AtlasView Multi-EO Release Monitor > Change 4

AM **Change 4** Draft
follows VAL-REL-019 automated review released 9 Sept

 **Documents** 2 · 1 changed  **Add files**

 **Drop PDFs here** · section guessed from the filename, you confirm

 **IFU & labelling** 1 document

☐ **multi-eo-product-label.pdf**
Replaces previous

VAL-REL-019 corrected [TEST] Harborline Im...  ...

d9e0d654

1 unchanged documents [Show all](#)

Ready to release? **Ready**

 **Every upload has a section.**
Settings / Review policy · Documents

 **Your organisation's country is not this device's market, so the release needs a confirmed authorised representative — appoint one under Who receives it, then confirm.**
Who receives it · Release authority & reviewers · recommended — you can still release
MDIS compares your organisation's country (from its SRN) with this device's market. Your representative is appointed under Who receives it — a partner you are already connected to at once, a new one once they accept the invitation. Confirming records that the appointment covers this market.
Confirm the appointment
[Open Who receives it](#)

Capture SHA-256: caa827ad29083840009e8e732bc6c34ca219f454890eec0f1a6bfc3adfa5acc8

27

EXECUTED GHERKIN STEP

And I release this tracked candidate once PASS

 **Technical file** 

  **[TEST] Northstar Medical Im...**  

Home > AtlasView Multi-EO Release Monitor > Change 4

 **Change 4** Draft
follows VAL-REL-019 automated review released 9 Sept

 **Documents** 2 · 1 changed  **Add files**

 **Drop PDFs here** · section guessed from the filename, you confirm

 **IFU & labelling** 1 document

☐

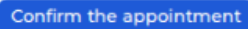
multi-eo-product-label.pdf
Replaces previous

VAL-REL-019 corrected
d9e0d654 [TEST] Harborline Im...  ...

1 unchanged documents [Show all](#)

Ready to release? Ready

 **Every upload has a section.**
Settings / Review policy · Documents

 **Your organisation's country is not this device's market, so the release needs a confirmed authorised representative — appoint one under Who receives it, then confirm.**
Who receives it · Release authority & reviewers · recommended — you can still release
MDIS compares your organisation's country (from its SRN) with this device's market. Your representative is appointed under Who receives it — a partner you are already connected to at once, a new one once they accept the invitation. Confirming records that the appointment covers this market.
 [Open Who receives it](#)

Capture SHA-256: 9254a9354fa8eb7d7942fb249a1d52ba646839a4159dcf07a13805e387f7cb46

28

EXECUTED GHERKIN STEP

Then delivery is visibly waiting for its blocking decision **PASS**

 Technical file 

  [TEST] Northstar Medical Im...  

Home > AtlasView Multi-EO Release Monitor > Change 4

 **Change 4**  Waiting
follows VAL-REL-019 automated review released 9 Sept

 **Documents** 2 · 1 changed · frozen as released

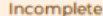
 **IFU & labelling** 1 document

multi-eo-product-label.pdf
Replaces previous

VAL -
REL - 019
corrected
d9e0d654

[TEST] Harborline Im...  ...

1 unchanged documents [Show all](#)

 **Registration**  Incomplete
28 of 65 answers · EUDAMED XML needs all 65 · not needed to release
[Answer remaining 37](#)
[Open registration](#)

Who receives it Choose who

 **[TEST] Harborline Importers**
Importer · IFU & labelling · 1 document · ...

Approvals, in order

1 **E2E Authorised Rep Co**  Now
Approver · Asked now

2 **[TEST] Harborline Importers**  Now
Reviewer · Asked now

Capture SHA-256: c7bfa64724bf9df30ac0c7e32ede0abaf8ed2004397b999bd0d2a163cf67c6d

29

EXECUTED GHERKIN STEP

When the authorised representative takes over the anchored-feedback review PASS

 Technical file ↕

↻ EA E2E Authorised Rep Co ↕ EA
Authorised Representative

Your work › AtlasView Multi-EO Release Monitor › VAL-REL-019 automated review

AM **Approve the release** Returned

[TEST] Northstar Medical Imaging · released 9 Sept · 2 documents · you requested changes · not delivered

Decision recorded.

You requested changes. Delivery stopped; the manufacturer sees your findings at the top of their change page.

[Back to your work](#)

Capture SHA-256: 72b7334962fa2856e14d07749368f122ddeb93f81f96cbaa717e999a034ea11a

30 EXECUTED GHERKIN STEP
And I open the exact anchored-feedback approval from the work queue PASS

 Technical file 

  E2E Authorised Rep Co
Authorised Representative  

 **Approve the release** **Frozen release documents** 2 documents

eifu-multilingual.pdf

multi-eo-product-label.pdf · VAL-REL-019 corrected d9e0d654

PDF review Exact revision Download

Page 1

E2E multilingual IFU - English / Nederlands

+

Capture SHA-256: 44766d12181445b73394eff1179dcbb79070e50e2a3f9c35fb45923a1adec330

31

EXECUTED GHERKIN STEP

Then the reviewer sees the carried finding without a stale anchor **PASS**

The screenshot displays the MedQAIR interface. At the top, the MedQAIR logo is on the left, and the user profile 'E2E Authorised Rep Co' is on the right. The main header shows 'Technical file' with a dropdown arrow. Below the header, there's a large empty box for a document. Underneath, a section titled 'Start a feedback thread' contains three tabs: 'Whole document', 'Page 1', and 'Region'. A text input field is labeled 'Describe what needs attention'. Below this are two more tabs: 'Blocks approval' and 'Note only'. A note states: 'Blocking findings go to the manufacturer with "Request changes". Notes travel with either decision and never hold anything.' An 'Open thread' button is at the bottom of this section. The next section, 'Findings on this document', shows '1 blocking' finding. The finding text is 'Move the highlighted product label away from the fold line.' It has two status tags: 'Addressed' (orange) and 'Blocking' (red). The origin is '21dc34d8-7dbb-4d5a-ad3d-09b3fa616fb0'. The finding is attributed to 'reviewer' with the text 'Move the highlighted product label away from the fold line.' and to 'manufacturer' with the text 'Corrected label proof prepared; the instructions remain unchanged.'

Capture SHA-256: da24a41439a36373f2f176a9a9fb9a2e26b901773b4e00f28ddb3d27e5c1cdda

32

EXECUTED GHERKIN STEP

When I resolve the carried anchored finding PASS

 Technical file 

  E2E Authorised Rep Co
Authorised Representative  

Findings on this document 1 blocking

Move the highlighted product label away from the fold line.
Resolved Blocking Origin: 21dc34d8-7dbb-4d5a-ad3d-09b3fa616fb0
reviewer
Move the highlighted product label away from the fold line.
manufacturer
Corrected label proof prepared; the instructions remain unchanged.

Reply

Reopen

Your decision Approver · E2E Authorised Rep Co

Your approval is your Article 11 verification of this release.

✓ Approve

 Request changes

Record decision

Capture SHA-256: cd0bef2a1ac6dc0381e02a799e73c3e0a4f10a11bc7a18c765ed61dd37ec030b

33

EXECUTED GHERKIN STEP

And I approve the anchored-feedback successor PASS

 Technical file 

  E2E Authorised Rep Co
Authorised Representative  

Your work › AtlasView Multi-EO Release Monitor › Change 4

AM

Approve the release

Delivered

[TEST] Northstar Medical Imaging · released 9 Sept · 2 documents · your approval is your verification of this release

Decision recorded.

You approved this release. If you were the last approver, delivery has started by itself.

[Back to your work](#)

Capture SHA-256: ac6d14471a67ec06a8dc32b363af00dc980bc3a39ca3f7f6d4e0b3b56ee88453

34

EXECUTED GHERKIN STEP

Then the anchored-feedback approval decision is durably recorded **PASS**

No visible change at this step; the terminal Decision recorded card was already visible after the decision action

 **Technical file** 

 **EA** **E2E Authorised Rep Co**  **EA**
Authorised Representative

Your work › AtlasView Multi-EO Release Monitor › Change 4

AM **Approve the release** **Delivered**

[TEST] Northstar Medical Imaging · released 9 Sept · 2 documents · your approval is your verification of this release

Decision recorded.

You approved this release. If you were the last approver, delivery has started by itself.

[Back to your work](#)

Capture SHA-256: ac6d14471a67ec06a8dc32b363af00dc980bc3a39ca3f7f6d4e0b3b56ee88453

35

EXECUTED GHERKIN STEP

When the Manufacturer resumes the anchored-feedback release **PASS**

 **Technical file** 

  **[TEST] Northstar Medical Im...**  

Home > AtlasView Multi-EO Release Monitor > Change 4

AM **Change 4** **Waiting**
follows Change 4 released 9 Sept

 **Documents** 2 · 1 changed · frozen as released

 **IFU & labelling** 1 document

multi-eo-product-label.pdf

Replaces previous

VAL -
REL - 019
corrected
d9e0d654

[TEST] Harborline Im...

 ...

1 unchanged documents [Show all](#)

 **Registration** **Incomplete**
28 of 65 answers · EUDAMED XML needs all 65 · not needed to release
[Answer remaining 37](#)
[Open registration](#)

Who receives it Choose who

 **[TEST] Harborline Importers**
Importer · IFU & labelling · 1 document · ...

Approvals, in order

1 **E2E Authorised Rep Co** **Now**

Approver · Asked now

2 **[TEST] Harborline Importers** **Now**

Reviewer · Asked now

Capture SHA-256: 3bb80dbcad1ec512a3806948187501b22082122c35721b361059c34becf4cbf6

36

EXECUTED GHERKIN STEP

And I reopen the tracked release **PASS**

 **Technical file** 

  **[TEST] Northstar Medical Im...**  

Home > AtlasView Multi-EO Release Monitor > Change 4

AM **Change 4** **Delivered**
on the market since 9 Sept

 **Documents** 2 · 1 changed · frozen as released

 **IFU & labelling**

1 document

multi-eo-product-label.pdf

Replaces previous

VAL -
REL - 019
corrected
d9e0d654

[TEST] Harborline Im...





1 unchanged documents

Show all

 **Registration** **Incomplete**

28 of 65 answers · EUDAMED XML needs all 65 · not needed to release

Answer remaining 37

Open registration

Who receives it Choose who

 **[TEST] Harborline Importers**

Importer · IFU & labelling · 1 document

Approvals, in order

 **E2E Authorised Rep Co**

Approver · Approved 9 Sept

2 **[TEST] Harborline Importers**

Reviewer · Asked now **Now**

Capture SHA-256: 6f0ec51a6838430b8927aa6ed557d688bb40880275452e53056f4764a0327ef1

37

EXECUTED GHERKIN STEP

Then the tracked release is delivered without another Release action PASS

No visible change at this step; the delivered projection remains visibly shown without another Release action

Evidence note: This passing assertion is limited to Delivered state and the absence of another Release action. A self-predecessor header and missing version name were recorded as a product finding on #1130; this step does not prove header lineage or closure of that finding. [Source record](#)

The screenshot displays the MedQAIR Technical file interface. At the top, the MedQAIR logo is on the left, and a 'Technical file' dropdown menu is next to it. On the right, there are navigation icons and a dropdown menu showing '[TEST] Northstar Medical Im...' with a 'Manufacturer' label and an 'EM' icon.

The main content area shows a breadcrumb trail: 'Home > AtlasView Multi-EO Release Monitor > Change 4'. Below this, a green box labeled 'AM' contains the text 'Change 4' and 'on the market since 9 Sept', with a green 'Delivered' status tag.

On the left, there are two sections: 'Documents' (2 · 1 changed · frozen as released) and 'IFU & labelling' (1 document). The 'IFU & labelling' section shows a document titled 'multi-eo-product-label.pdf' with the description 'Replaces previous'. To the right of the document title, it says 'VAL - REL - 019 corrected d9e0d654 [TEST] Harborline Im...' with an eye icon and a menu icon. Below this, it says '1 unchanged documents' and a 'Show all' link.

On the right, there are three sections: 'Registration' (Incomplete), 'Who receives it' (Choose who), and 'Approvals, in order'. The 'Registration' section shows '28 of 65 answers · EUDAMED XML needs all 65 · not needed to release' and buttons for 'Answer remaining 37' and 'Open registration'. The 'Who receives it' section shows '[TEST] Harborline Importers' as the importer for IFU & labelling with 1 document. The 'Approvals, in order' section shows a list of approvals, including 'E2E Authorised Rep Co' (Approver · Approved 9 Sept) and '[TEST] Harborline Importers' (Reviewer · Asked now) with a 'Now' button.

Capture SHA-256: 6f0ec51a6838430b8927aa6ed557d688bb40880275452e53056f4764a0327ef1

38 EXECUTED GHERKIN STEP
And fresh reads reconstruct the anchored-feedback release history PASS

No visible change at this step; asserted through the API read

 **Technical file** 

 TN **[TEST] Northstar Medical Im...**  EM

Home › AtlasView Multi-EO Release Monitor › Change 4

AM

Change 4 Delivered

on the market since 9 Sept

Delivered to the frozen recipient set

 **Documents** 2 · 1 changed · frozen as released

 **IFU & labelling**

1 document

 **multi-eo-product-label.pdf**

Replaces previous

VAL -
REL - 019
corrected
d9e0d654

[TEST] Harborline Im...





1 unchanged documents

[Show all](#)

 **Registration** Incomplete

28 of 65 answers · EUDAMED XML needs all 65 · not needed to release

Answer remaining 37

Open registration

Who receives it Choose who

TH **[TEST] Harborline Importers**

Importer · IFU & labelling · 1 document

Approvals, in order

 **E2E Authorised Rep Co**

Approver · Approved 9 Sept

2 **[TEST] Harborline Importers** Now

Reviewer · Asked now

Capture SHA-256: 6f0ec51a6838430b8927aa6ed557d688bb40880275452e53056f4764a0327ef1

39

EXECUTED GHERKIN STEP

When the unrelated Manufacturer takes over for the isolation check PASS

 Technical file 

 E2E Foreign Manufacturer Co  
Manufacturer

Your work

E2E Foreign Manufacturer Co · Wednesday 9 September

 **0**
drafts to finish

 **0**
returned for changes

 **0**
waiting on a partner

 **2**
devices, 0 released

 Add a device

Needs you


Nothing needs you.

Devices · 2

[All 2 >](#)

 Northgate Unrelated Ten...

Unreleased

 ForeignScope Imaging C...

Unreleased

Capture SHA-256: 0793b981fd44f103adc7ff466583e9630230d84019cec35e3931e871343a63dc

40

EXECUTED GHERKIN STEP

And I try to read and mutate the exact anchored feedback PASS



Technical file ▾



EF

E2E Foreign Manufacturer Co
Manufacturer ▾

EF

This change is not
available. [Back to the
device](#)

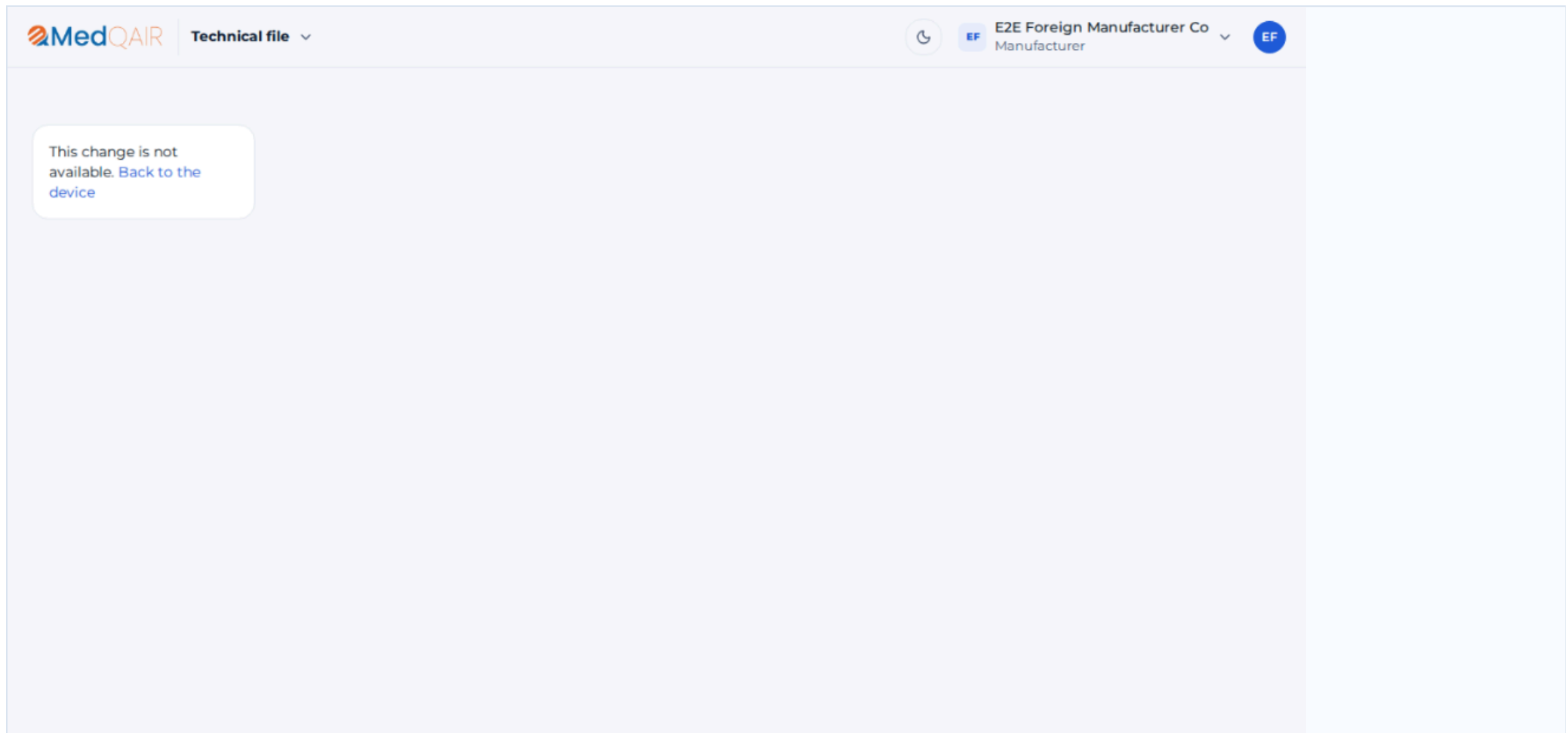
Capture SHA-256: 4c6bc09e9e2249f712303eec7a361b753a67200559bb974ab5e20f563b175cfe

41

EXECUTED GHERKIN STEP

Then the foreign anchored-feedback view is non-disclosing and has no lifecycle actions PASS*No visible change at this step; the foreign view remains visibly non-disclosing*

Evidence note: Negative control: an unrelated manufacturer attempted to read and mutate this exact release feedback. The preceding API assertions and this non-disclosing screen prove this tested boundary; they are not a complete tenant-isolation assessment.



Capture SHA-256: 4c6bc09e9e2249f712303eec7a361b753a67200559bb974ab5e20f563b175cfe

Partner access

A partner connection is established without granting document access before a release is explicitly shared.

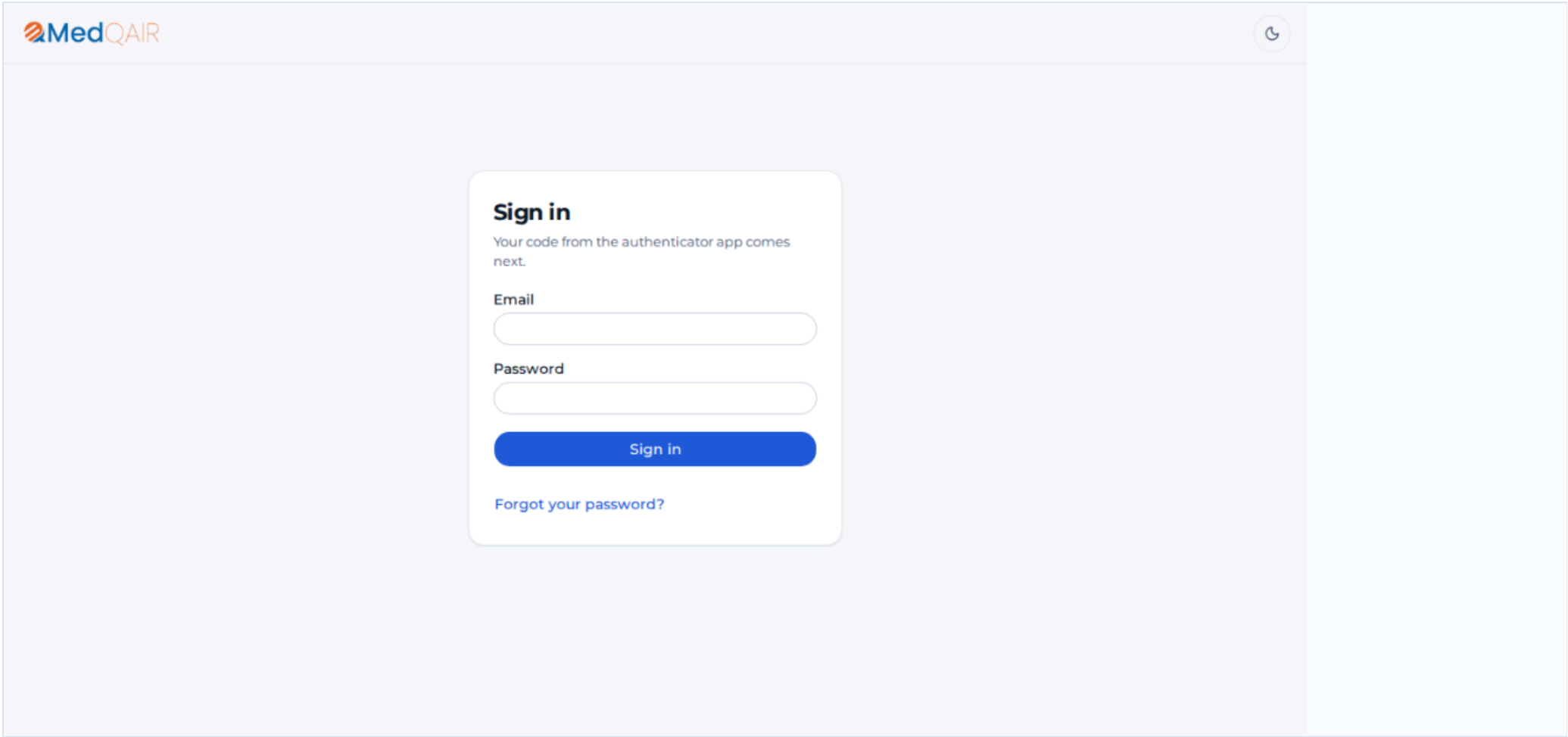
S02 onboards a partner without a release or document access

01

EXECUTED GHERKIN STEP

Given the redesign sign-in page

PASS



Capture SHA-256: 953d9a1220a1b501a0ede3a87b7d5516c6552f0e0d727f3b59246c01ef255e3b

02

EXECUTED GHERKIN STEP

When I sign in to the redesign as a manufacturer **PASS**

 Technical file 

   [TEST] Northstar Medical Im...  

Your work

[TEST] Northstar Medical Imaging · Wednesday 9 September

 **4**
drafts to finish

 **0**
returned for changes

 **0**
waiting on a partner

 **22**
devices, 5 released

 Add a device

Needs you

4 drafts

 **Northstar VitalSync Patient Monitor**
1.1 labelling update 

 **Northstar SonoLite Handheld Ultrasound**
1.0 first release 

 **Northstar CardioMesh Coronary Stent**
1.0 first release 

 **Northstar LumaDerm Phototherapy Lamp**
Change 1 · first release 

Devices · 22

All 22 >

 **PulseView AR Validation ...** 

 **AtlasView PRRC Validatio...** 

 **AtlasView AR Verification ...** 

 **AtlasView AR Validation ...** 

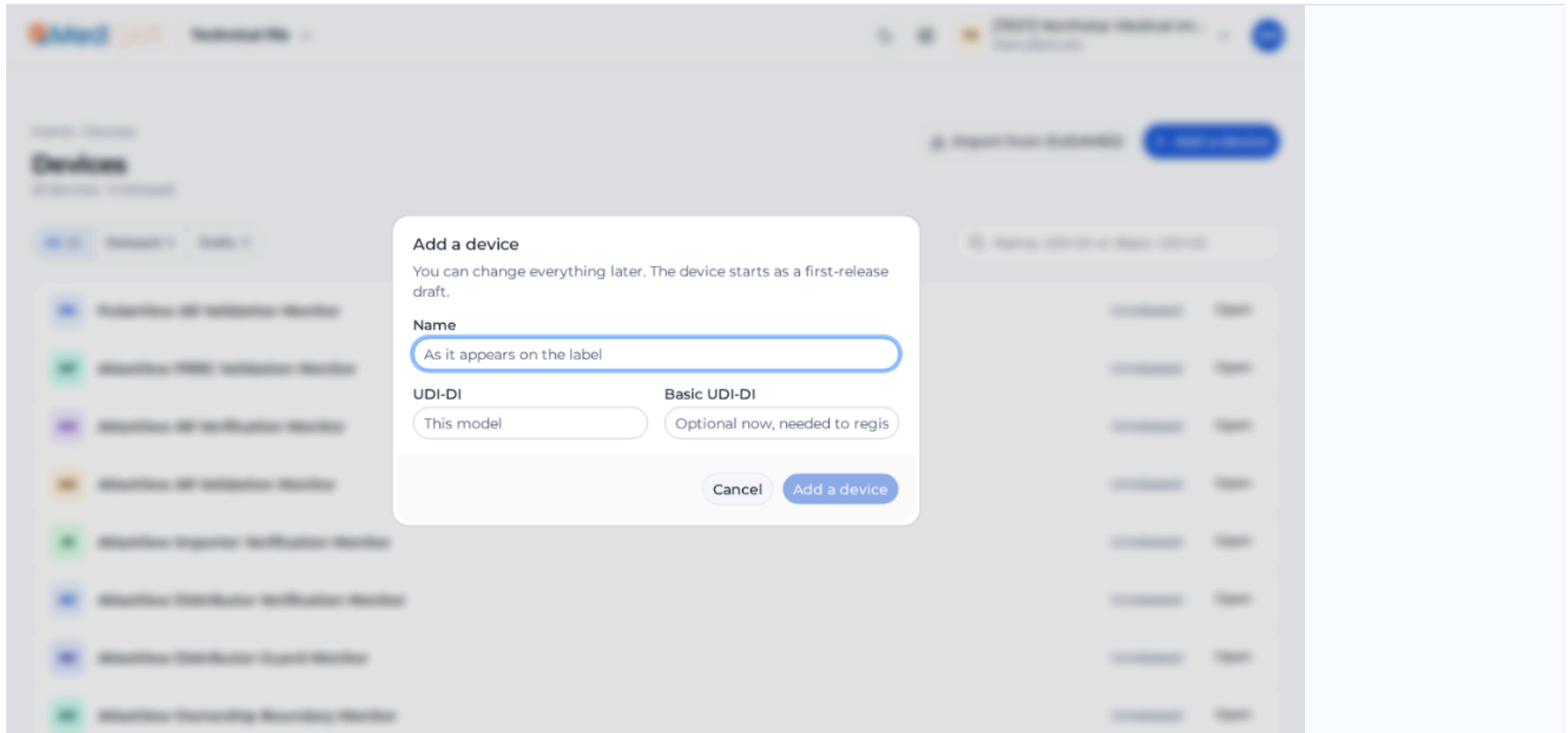
 **AtlasView Importer Verifi...** 

 **AtlasView Distributor Veri...** 

Capture SHA-256: 3a2cca4761783618bc46e0c0686b80d1e5c6508771e99b30da3b1178ea6de45f

03

EXECUTED GHERKIN STEP

And I open the redesign's add-device form **PASS**

Capture SHA-256: b4b66143a5882ee2d69b3077fca604a10449f0819742967169a0c7fba5ded04e

04

EXECUTED GHERKIN STEP

And I submit a device with a unique name and UDI-DI PASS

 Technical file 

  [TEST] Northstar Medical Im...  

Home > Devices > E2E Journey Device 1788933562551433

 **E2E Journey Device 1788933562551433** Unreleased
not released yet · Basic UDI-DI —

Choose who  Start first release

Changes and releases

No changes yet.

Registration Open

Not started. EUDAMED needs every answer.

Who can open it Choose who

Only you, so far.

Identification

UDI-DI
E2E-1788933562551433

Basic UDI-DI
—

UDI-PI
—

Capture SHA-256: 8e8d06bf68c101dcde27a98452be8132f1bcc487ad5dbe352bcdb5379aa1815

05

EXECUTED GHERKIN STEP

And I open the device's access page PASS

 Technical file 

  [TEST] Northstar Medical Im...  

Home > E2E Journey Device 1788933562551433 > Who receives it Back to the device



Who receives it

Who can open E2E Journey Device 1788933562551433's documents.

Current access

Open Access from a draft change to choose the exact documents each partner will receive. Existing released access is shown here for reference.

What each partner gets

No company is on this device yet, so there is no one to share with.

Choose a company... 

+ Add to this device

Invite a new company

Adding a company does not share anything yet — you choose what they can open next.

Access trail

Nothing recorded yet.

Capture SHA-256: 337f9d1989e3f50bd017ae4f3710d1c88f9842a7d375d7e3d8e7eec80a1b0dbb

06

EXECUTED GHERKIN STEP

And I add the authorised representative to this device PASS

 Technical file 

  [TEST] Northstar Medical Im...  

Home > E2E Journey Device 1788933562551433 > Who receives it Back to the device



Who receives it

Who can open E2E Journey Device 1788933562551433's documents.

Current access

Open Access from a draft change to choose the exact documents each partner will receive. Existing released access is shown here for reference.

What each partner gets

 **E2E Authorised Rep Co** Not shared
Authorised representati...

Choose a company... 

 Add to this device

Invite a new company

Adding a company does not share anything yet — you choose what they can open next.

Access trail

Nothing recorded yet.

Capture SHA-256: 73813586634f6537a66c66bc344df52f5ea83bc4c98a34e14925eb9aa0c8e0b5

07

EXECUTED GHERKIN STEP

Then the authorised representative is connected with no document access **PASS***No visible change at this step; the asserted state was already present*

MedQAIR Technical file ▼ ⌂ TN [TEST] Northstar Medical Im... ▼ EM
Manufacturer

Home > E2E Journey Device 1788933562551433 > Who receives it Back to the device

Who receives it

Who can open E2E Journey Device 1788933562551433's documents.

Current access

Open Access from a draft change to choose the exact documents each partner will receive. Existing released access is shown here for reference.

What each partner gets

EA **E2E Authorised Rep Co** Not shared
Authorised representati...

Choose a company... ▼

+ Add to this device

Invite a new company

Adding a company does not share anything yet — you choose what they can open next.

Access trail

Nothing recorded yet.

Capture SHA-256: 73813586634f6537a66c66bc344df52f5ea83bc4c98a34e14925eb9aa0c8e0b5

08

EXECUTED GHERKIN STEP

And the device access projection persists the connected zero-access relation PASS

No visible change at this step; asserted through the API read

 **Technical file** 

 TN **[TEST] Northstar Medical Im...**  EM

Home > E2E Journey Device 1788933562551433 > Who receives it

 **Who receives it**
Who can open E2E Journey Device 1788933562551433's documents.

Current access

Open Access from a draft change to choose the exact documents each partner will receive. Existing released access is shown here for reference.

What each partner gets

EA **E2E Authorised Rep Co** Not shared
Authorised representati...

Choose a company... 

+ Add to this device

Invite a new company

Adding a company does not share anything yet — you choose what they can open next.

Access trail

Nothing recorded yet.

[Back to the device](#)

Capture SHA-256: 73813586634f6537a66c66bc344df52f5ea83bc4c98a34e14925eb9aa0c8e0b5

MDIS walkthrough · 137 / 418

09

EXECUTED GHERKIN STEP

And the run-owned device has no release or version persisted PASS*No visible change at this step; asserted through the API read*

 **Technical file** 

 TN [TEST] Northstar Medical Im...  EM

Home > E2E Journey Device 1788933562551433 > Who receives it

 **Who receives it**
Who can open E2E Journey Device 1788933562551433's documents.

[Back to the device](#)

Current access

Open Access from a draft change to choose the exact documents each partner will receive. Existing released access is shown here for reference.

What each partner gets

EA **E2E Authorised Rep Co** Not shared
Authorised representati...

Choose a company... 

[+ Add to this device](#)

[Invite a new company](#)

Adding a company does not share anything yet — you choose what they can open next.

Access trail

Nothing recorded yet.

Capture SHA-256: 73813586634f6537a66c66bc344df52f5ea83bc4c98a34e14925eb9aa0c8e0b5

Instructions for use, public

A manager publishes released instructions and then stops their public availability.

features/eifu/publish-instructions.feature · @SR-143 @MODULE:EIFU-PORTAL @UR-013 @UR-020 @RSK-002

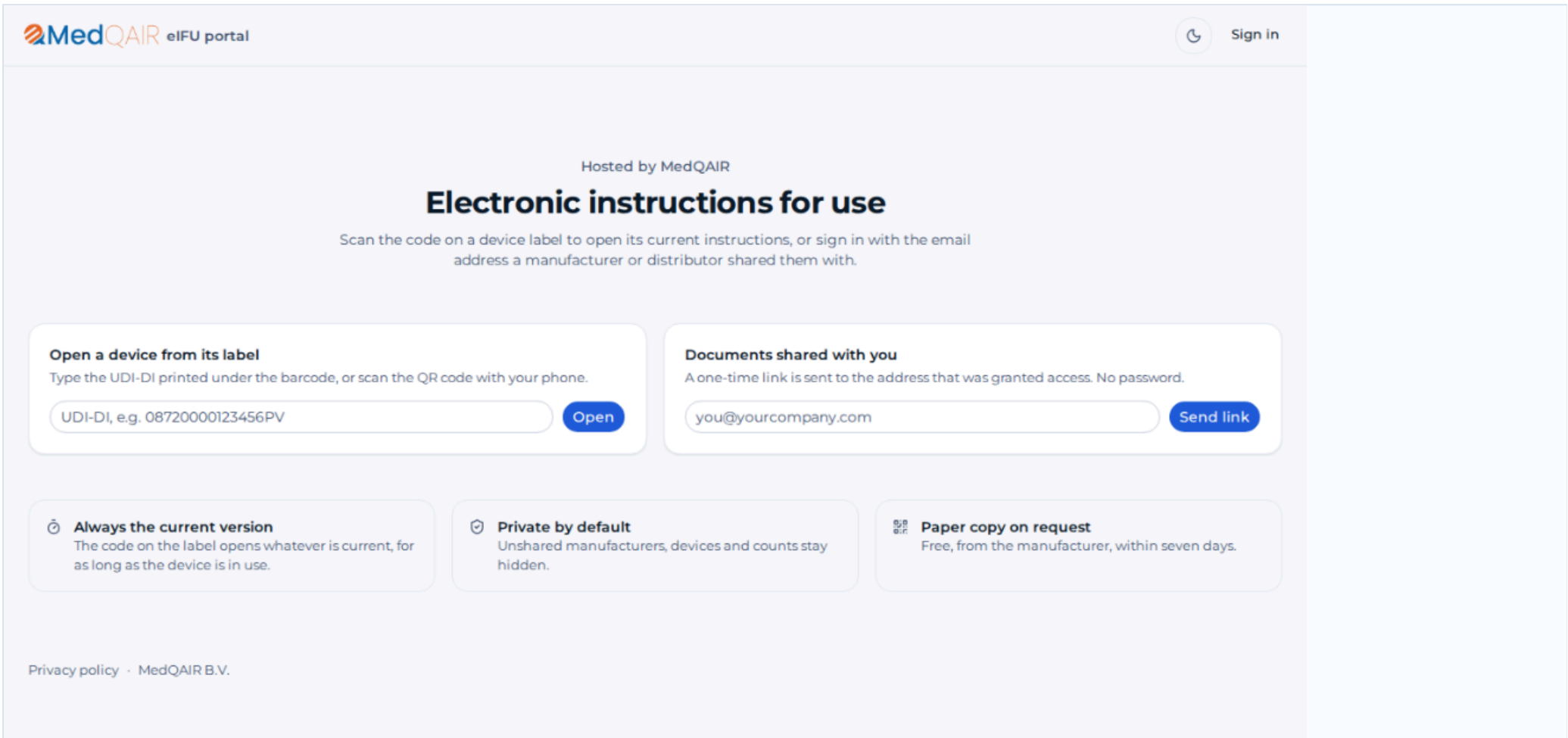
PASS

A manager publishes a device and later stops public access

01

EXECUTED GHERKIN STEP

Given NeuroScan starts without an active eIFU publication PASS



Capture SHA-256: aca943c51ba4aa880f5eb1ac7a7ead781664d88b6ce38668ee2031af4c32f354

02

EXECUTED GHERKIN STEP

And the manufacturer manager is signed in to the redesign PASS

 Technical file 

 TN [TEST] Northstar Medical Im...  EM

EM

Northstar Medical Imaging

Wednesday 9 September

+ Add a device

 **5**
drafts to finish

 **0**
returned for changes

 **0**
waiting on a partner

 **27**
devices, 5 released

Needs you

5 drafts

 **NC**

Northstar CardioMesh Coronary Stent

1.0 first release

Continue

 **NL**

Northstar LumaDerm Phototherapy Lamp

Change 1 - first release

Continue

 **NS**

Northstar SonoLite Handheld Ultrasound

1.0 first release

Continue

 **NV**

Northstar VitalSync Patient Monitor

1.1 labelling update

Continue

 **E2E**

E2E Journey Device 1788933641806128

Change 1 - 1.0.0 - first release

Continue

Devices · 27

All 27 >



Name, UDI-DI or Basic UDI-DI

 **PA**

PulseView AR Validation ...

Unreleased

 **AI**

AtlasView Importer Verifi...

Unreleased

 **AA**

AtlasView AR Verification ...

Unreleased

 **AD**

AtlasView Distributor Veri...

Unreleased

 **AD**

AtlasView Distributor Gu...

Unreleased

 **AO**

AtlasView Ownership Bo...

Unreleased

Capture SHA-256: ab9b8a79765c43eb53b7973e41c92e70c4b0122f92f96f30f73f422d117abcf

MDIS walkthrough · 141 / 418

03

EXECUTED GHERKIN STEP

And the manager opens Published instructions **PASS**

The screenshot displays the 'Published instructions' page in the MedQAIR system. The top header includes the MedQAIR logo, a 'Technical file' dropdown, and user information for '[TEST] Northstar Medical Im...' with a role of 'Manufacturer'. The sidebar on the left contains navigation links for 'Home', 'Organisation' (Bulk import, Organisation facts, Users, Partners), 'RELEASES' (Published instructions, Release checks, Release history, History), and 'ACCOUNT' (Sign-in and MFA). The main content area features three summary cards: '0 devices with instructions online', '0 current documents, 0 languages', and '0 requests waiting'. Below these are filters for 'All 27', 'Public 0', 'Shared 1', and 'Unpublished 26', along with a search bar 'Find a device'. A list of six device instructions is shown, each with a status (e.g., 'Shared', 'Unpublished') and an 'Open change' link.

Device Name	Status	Action
PulseView AR Validation Monitor	Shared	Who can open
AtlasView Importer Verification Monitor	Unpublished	Open change
AtlasView AR Verification Monitor	Unpublished	Open change
AtlasView Distributor Verification Monitor	Unpublished	Open change
AtlasView Distributor Guard Monitor	Unpublished	Open change
AtlasView Ownership Boundary Monitor	Unpublished	Open change

Capture SHA-256: 74e0e74c424985019966eed1e88e01451c35ea65b8ccfaca340f1c22fd236735

04

EXECUTED GHERKIN STEP

When the manager publishes NeuroScan **PASS**

 Technical file 

  [TEST] Northstar Medical Im...  

	E2E Release Ledger Synthetic Device Released 1.0 on 9 Sept · not yet published	Unpublished	Open change	Publish
	Northstar CardioMesh Coronary Stent No instructions released yet · draft change open	Unpublished	Open change	
	Northstar AeroVent Home Ventilator No instructions released yet	Unpublished	Open change	
	Northstar LumaDerm Phototherapy Lamp No instructions released yet · draft change open	Unpublished	Open change	
	Northstar OxyTrack Pulse Oximeter Released 1.0 on 9 Sept · not yet published	Unpublished	Open change	Publish
	Northstar NeuroScan EEG Cap Rev 1.0 · en · from release 1.0 on 9 Sept	Public	 QR code	Who can open ...
	Northstar SonoLite Handheld Ultrasound No instructions released yet · draft change open	Unpublished	Open change	
	Northstar VitalSync Patient Monitor Released 1.0 on 9 Sept · not yet published	Unpublished	Open change	Publish
	E2E Journey Device 1788933562551433 No instructions released yet	Unpublished	Open change	
	E2E Journey Device 1788933568193872 No instructions released yet	Unpublished	Open change	
	E2E Journey Device 1788933579021643 No instructions released yet	Unpublished	Open change	

Capture SHA-256: abddf07848134d6c2d29a9deff6e4304d20c5e37bcbcb356ae40f919da17c1a

05

EXECUTED GHERKIN STEP

Then a separate anonymous visitor finds the NeuroScan instructions **PASS**

The screenshot displays the MedQAIR eIFU portal interface. At the top left is the MedQAIR logo and 'eIFU portal' text. At the top right is a 'Sign in' button. Below the header, the breadcrumb path reads 'eIFU portal > [TEST] Northstar Medical Imaging > Northstar NeuroScan EEG Cap'. To the right of the breadcrumb are 'Read' and 'Download PDF' buttons. The main content area features a large white box for instructions. To the right of this box are two sections: 'Earlier versions' and 'Manufacturer'. The 'Earlier versions' section states that no earlier version has been published and that the versions published here are not a record of every version. The 'Manufacturer' section lists '[TEST] Northstar Medical Imaging'.

MedQAIR eIFU portal

Sign in

eIFU portal > [TEST] Northstar Medical Imaging > Northstar NeuroScan EEG Cap

Read Download PDF

Instructions for use **Current**

Northstar NeuroScan EEG Cap - UDI-DI 09506000901077 - Rev 1.0 - 9 Sept 2026

Earlier versions

No earlier version has been published here.

These are the versions published here. It is not a record of every version this document has ever had.

Manufacturer

[TEST] Northstar Medical Imaging

Capture SHA-256: c85553b759e4c529880d8beaeb74a7ff58fd83ed35715a26683ef457fc5b00cf

06

EXECUTED GHERKIN STEP

When the manager stops public access to NeuroScan PASS

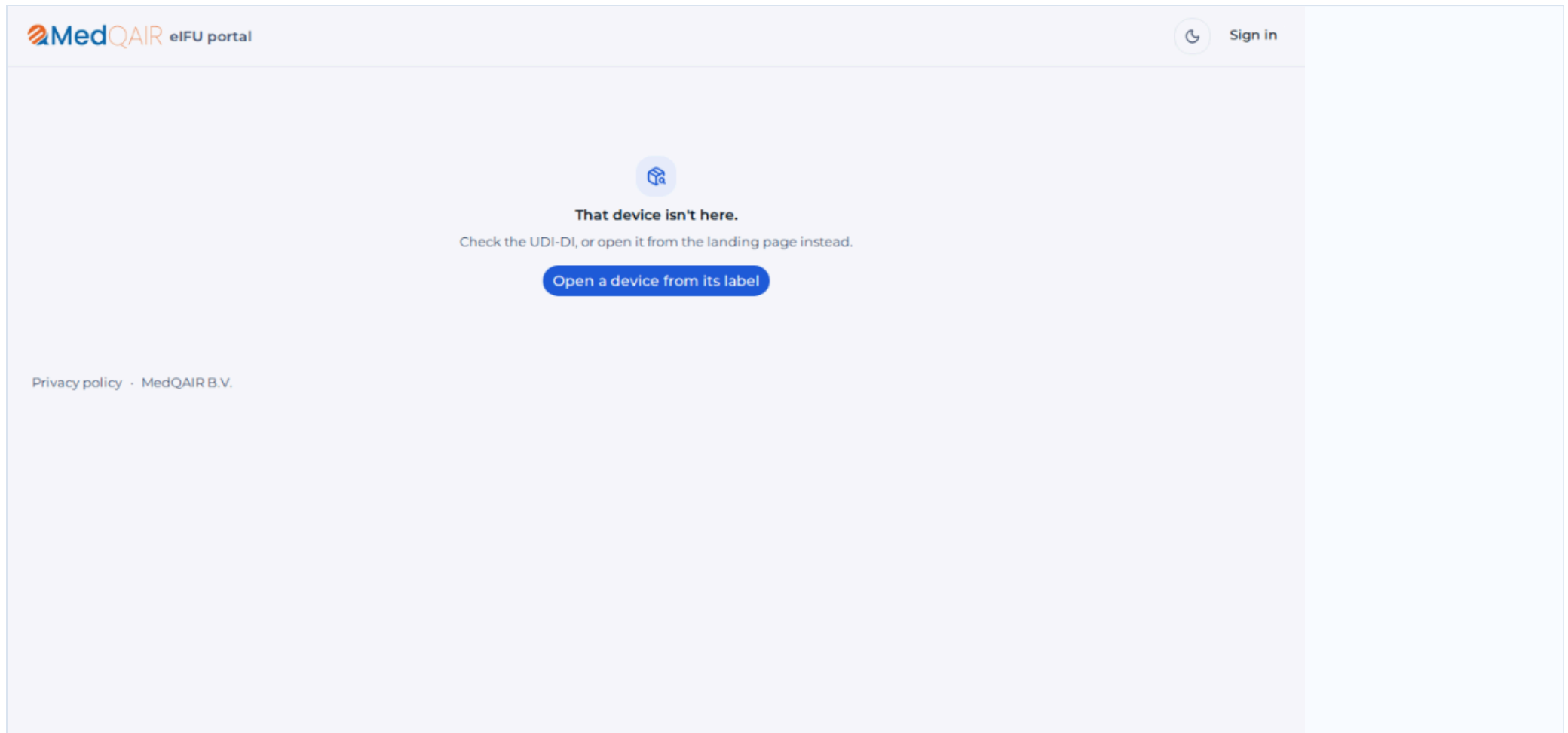
		Technical file ▾		  [TEST] Northstar Medical Im... ▾ 	
		E2E Release Ledger Synthetic Device Released 1.0 on 9 Sept · not yet published	Unpublished	Open change	Publish
		Northstar CardioMesh Coronary Stent No instructions released yet · draft change open	Unpublished	Open change	
		Northstar AeroVent Home Ventilator No instructions released yet	Unpublished	Open change	
		Northstar LumaDerm Phototherapy Lamp No instructions released yet · draft change open	Unpublished	Open change	
		Northstar OxyTrack Pulse Oximeter Released 1.0 on 9 Sept · not yet published	Unpublished	Open change	Publish
		Northstar NeuroScan EEG Cap Public access stopped on 9 Sept	Unpublished	Open change	Resume ...
		Northstar SonoLite Handheld Ultrasound No instructions released yet · draft change open	Unpublished	Open change	
		Northstar VitalSync Patient Monitor Released 1.0 on 9 Sept · not yet published	Unpublished	Open change	Publish
		E2E Journey Device 1788933562551433 No instructions released yet	Unpublished	Open change	
		E2E Journey Device 1788933568193872 No instructions released yet	Unpublished	Open change	
		E2E Journey Device 1788933579021643 No instructions released yet	Unpublished	Open change	

Capture SHA-256: d81682240ed2b328d55e435852a4a4953496af1520897f44e09e2fff8b14ecab

07

EXECUTED GHERKIN STEP

Then the same anonymous visitor no longer finds the NeuroScan instructions **PASS**



Capture SHA-256: 29e42e0c0892867fddee7ef7ec72d94521f9659ba708e9732012bdcc04b3be40

Vigilance

A manufacturer registers, assesses, and records the filing of a post-market event.

features/vigilance/coordinate-a-synthetic-event.feature · @SR-180 @SR-186 @SR-189 @MODULE:VIGILANCE @UR-023 @RSK-001 @RSK-022

PASS

A manufacturer registers an event, assesses it, and records the report it filed

01 EXECUTED GHERKIN STEP
Given I enter the controlled Vigilance workspace as the seeded manufacturer PASS

 Vigilance

 TN [TEST] Northstar Medical Im...
Manufacturer EM

Vigilance

[TEST] Northstar Medical Imaging · Sep 9, 2026

Register an event

2

overdue for reporting

0

due this week

4

events registered

1

closed, not reportable

Q

Find an event

Needs you

PMC-A5AFC4410D04

Unexpected shutdown during monitored infusion; fatal outcome reported

Overdue 25 days

PMC-116EE05CEB57

Intermittent flow-rate alarm during infusion; no injury reported

Overdue 17 days

Events

PMC-A5AFC4410D04

Unexpected shutdown during monitored infusion; fatal outcome repo...

Incident · your organisation

report was due Aug 15, 2026 · 25 days over

Overdue

PMC-116EE05CEB57

Intermittent flow-rate alarm during infusion; no injury reported

Malfunction · your organisation

report was due Aug 23, 2026 · 17 days over

Overdue

PMC-C16051R1A500

Current-stack neutral event 1788933836682

report due Sep 24, 2026 · 15 days left

Registered

Capture SHA-256: 32a352e605c193add2508bd7b96f6cf94656194d5ffa8485cc77f3f3f13f3cb3

02

EXECUTED GHERKIN STEP

When I register a neutral event with the device not yet identified **PASS**

 Vigilance 

  [TEST] Northstar Medical Im...  

Synthetic display interruption for controlled Vigilance journey 0 Registered

PMC-19D91B7A23A0 · Malfunction · your organisation · opened Sep 9, 2026

 **When it happened**

OCCURRED
Not recorded
Not recorded

MANUFACTURER AWARENESS
Not recorded
Not yet confirmed

REGISTERED
Sep 9, 2026
Recorded by MDIS

Three dates, three facts — clocks count from the confirmed awareness of the legal reporter, nothing else.

 **Affected device**

Device unresolved
No identifier snapshot

The event records which device, not which unit — no lot or serial number was captured with it.

 **Assessments & clocks** Record assessment

No obligation has been assessed. Registering an event does not start a regulatory clock.

 **Reports filed**

Capture SHA-256: df5a839040bb441693ad2f1e35fba7ec61a89e1cff56696e486d04e42f616204

03

EXECUTED GHERKIN STEP

Then the case exists with no clock until someone assesses it **PASS***No visible change at this step; the asserted UI state remains visible*

 **Vigilance** 

  [TEST] Northstar Medical Im...  

Synthetic display interruption for controlled Vigilance journey 0 Registered

PMC-19D91B7A23A0 · Malfunction · your organisation · opened Sep 9, 2026

 **When it happened**

OCCURRED
Not recorded
Not recorded

MANUFACTURER AWARENESS
Not recorded
Not yet confirmed

REGISTERED
Sep 9, 2026
Recorded by MDIS

Three dates, three facts — clocks count from the confirmed awareness of the legal reporter, nothing else.

 **Affected device**

Device unresolved
No identifier snapshot

The event records which device, not which unit — no lot or serial number was captured with it.

 **Assessments & clocks**

Record assessment

No obligation has been assessed. Registering an event does not start a regulatory clock.

 **Reports filed**

Capture SHA-256: df5a839040bb441693ad2f1e35fba7ec61a89e1cff56696e486d04e42f616204

04

EXECUTED GHERKIN STEP

When I record the assessment as another serious incident, aware four days ago PASS

 Vigilance   [TEST] Northstar Medical Im... 

Synthetic display interruption for controlled Vigilance journey 0 Registered

PMC-19D91B7A23A0 · Malfunction · your organisation · opened Sep 9, 2026

 **When it happened**

OCCURRED
Not recorded
Not recorded

MANUFACTURER AWARENESS
Sep 5, 2026
Recorded with assessment

REGISTERED
Sep 9, 2026
Recorded by MDIS

Three dates, three facts — clocks count from the confirmed awareness of the legal reporter, nothing else.

 **Affected device**

Device unresolved
No identifier snapshot

The event records which device, not which unit — no lot or serial number was captured with it.

 **Assessments & clocks** Record assessment

  **Other Serious Incident** · legal reporter: your organisation On track

Due Sep 20, 2026 · 11 days left
from Sep 5, 2026 · 15 calendar days · other serious incident

Capture SHA-256: 7903df7fb8092764eb8366da482ecb8ec7a6671bd1636b2d1a3f1b0cd40dcb9d

05

EXECUTED GHERKIN STEP

Then the deadline counts fifteen days from awareness and the register agrees PASS

 Vigilance ▼

 TN [TEST] Northstar Medical Im... ▼ EM

[← Vigilance](#)

Synthetic display interruption for controlled Vigilance journey 0 Registered

PMC-19D91B7A23A0 · Malfunction · your organisation · opened Sep 9, 2026

 **When it happened**

OCCURRED
Not recorded
Not recorded

MANUFACTURER AWARENESS
Sep 5, 2026
Recorded with assessment

REGISTERED
Sep 9, 2026
Recorded by MDIS

Three dates, three facts — clocks count from the confirmed awareness of the legal reporter, nothing else.

 **Affected device**

Device unresolved
No identifier snapshot

The event records which device, not which unit — no lot or serial number was captured with it.

 **Assessments & clocks**

Record assessment

 EU **Other Serious Incident** · legal reporter: your organisation

Due Sep 20, 2026 · 11 days left

On track

Capture SHA-256: 6af904c1587167f594cf9d14f7e6022d33cdfda181a9dad87f65e00cd4ee7658

06

EXECUTED GHERKIN STEP

When the manufacturer records that the report was filed with the authority PASS

 Vigilance   [TEST] Northstar Medical Im...  

Three dates, three facts — clocks count from the confirmed awareness of the legal reporter, nothing else.

 **Affected device**

Device unresolved
No identifier snapshot

The event records which device, not which unit — no lot or serial number was captured with it.

 **Assessments & clocks** Record assessment

  **Other Serious Incident** · legal reporter: your organisation Met

Reported Sep 9, 2026 · 11 days early · ref ICGJ-1788934093035
from Sep 5, 2026 · 15 calendar days · other serious incident

 **Reports filed** Mark as reported

 **Initial report** filed Sep 9, 2026 · ref ICGJ-1788934093035 · recorded by E2E Manufacturer Sep 9, 2026

Recorded, not filed — MDIS never submits to an authority on your behalf.

Capture SHA-256: 1b15faff9d61e83c9325c8459d5a1fbcf6729a012adefb55bbdb7372c96a948

07

EXECUTED GHERKIN STEP

Then the clock reads met and the register no longer counts it as owed PASS

 **Vigilance** 

  **[TEST] Northstar Medical Im...**  

[← Vigilance](#)

Synthetic display interruption for controlled Vigilance journey 0

Registered

PMC-19D91B7A23A0 · Malfunction · your organisation · opened Sep 9, 2026

 **When it happened**

OCCURRED
Not recorded
Not recorded

MANUFACTURER AWARENESS
Sep 5, 2026
Recorded with assessment

REGISTERED
Sep 9, 2026
Recorded by MDIS

Three dates, three facts — clocks count from the confirmed awareness of the legal reporter, nothing else.

 **Affected device**

Device unresolved
No identifier snapshot

The event records which device, not which unit — no lot or serial number was captured with it.

 **Assessments & clocks** Record assessment

  **Other Serious Incident** · legal reporter: your organisation Met

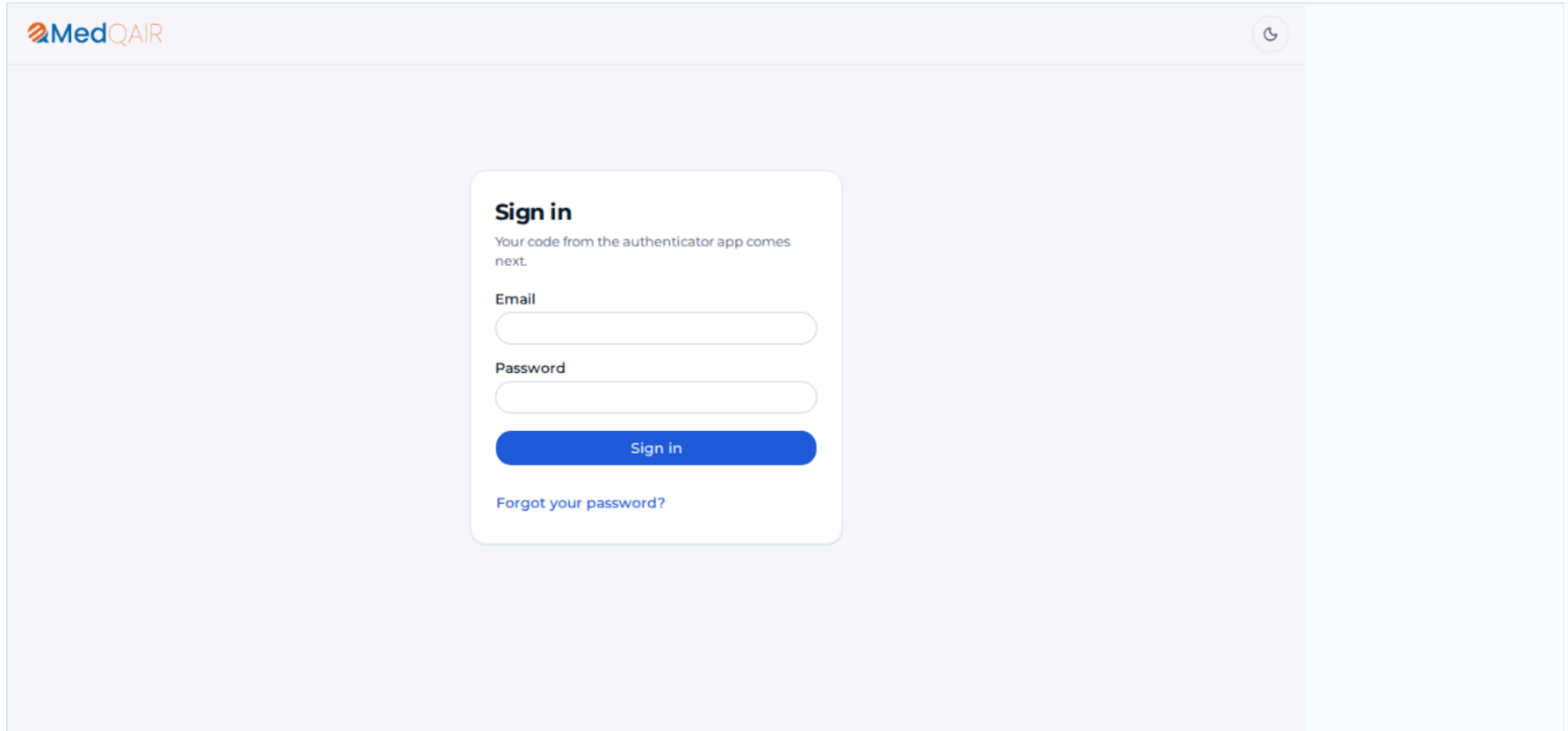
Reported Sep 9, 2026 · 11 days early · ref ICGJ-1788934093035

Capture SHA-256: 371363c0faba62a614f514be3135ce841219b601317ad9c7cb893748f00c9fba

08

EXECUTED GHERKIN STEP

When the final ui-v2 session is ended **PASS**



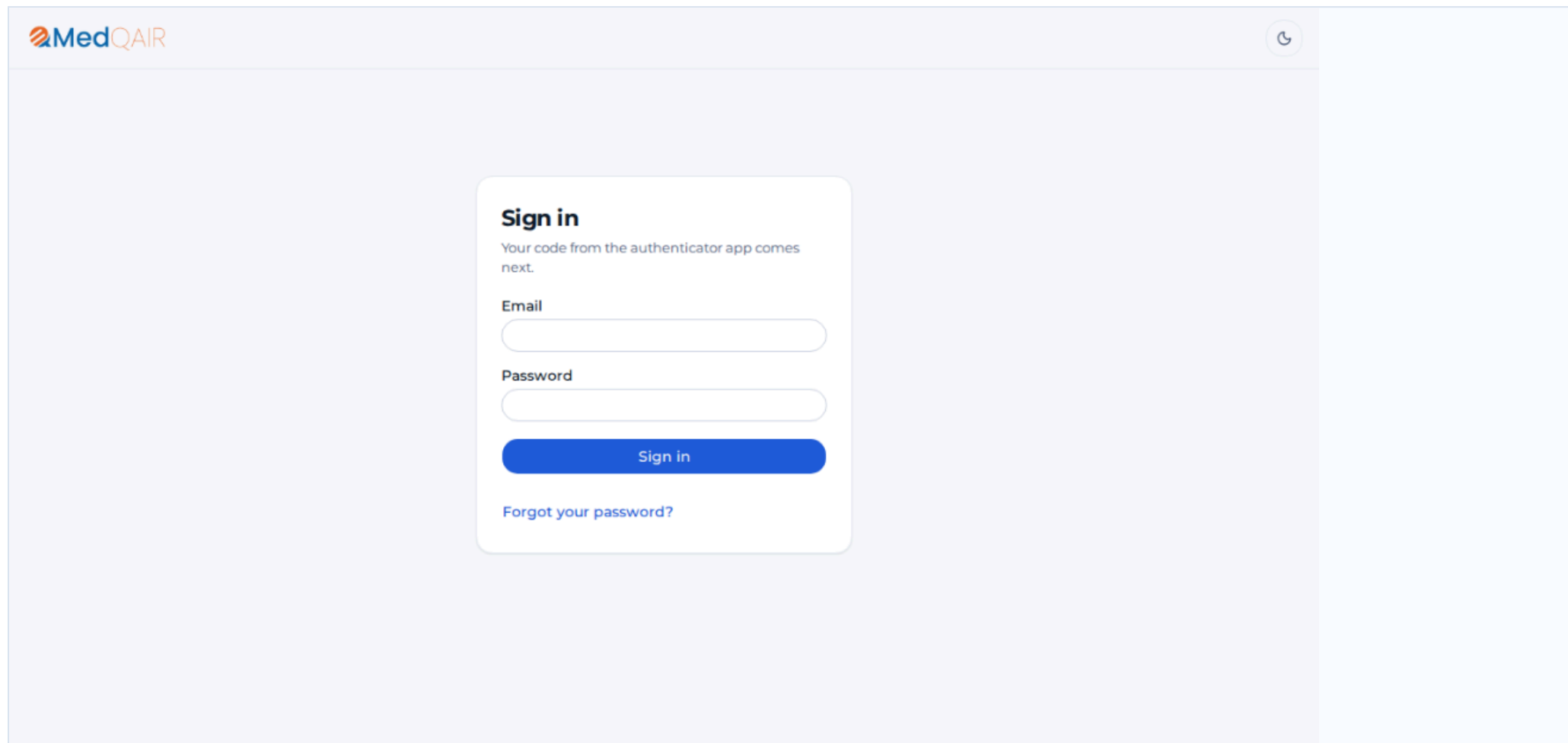
Capture SHA-256: 953d9a1220a1b501a0ede3a87b7d5516c6552f0e0d727f3b59246c01ef255e3b

09

EXECUTED GHERKIN STEP

Then no authenticated ui-v2 session remains in browser storage **PASS**

No visible change at this step; asserted through browser storage



Capture SHA-256: 953d9a1220a1b501a0ede3a87b7d5516c6552f0e0d727f3b59246c01ef255e3b

Platform administration

A system administrator provisions an organisation while a platform administrator reads and narrows the audit trail.

features/organisation-management/provision-organisation-in-ui-v2.feature · @MODULE:ORGANISATION-MANAGEMENT @SR-016 @UR-001

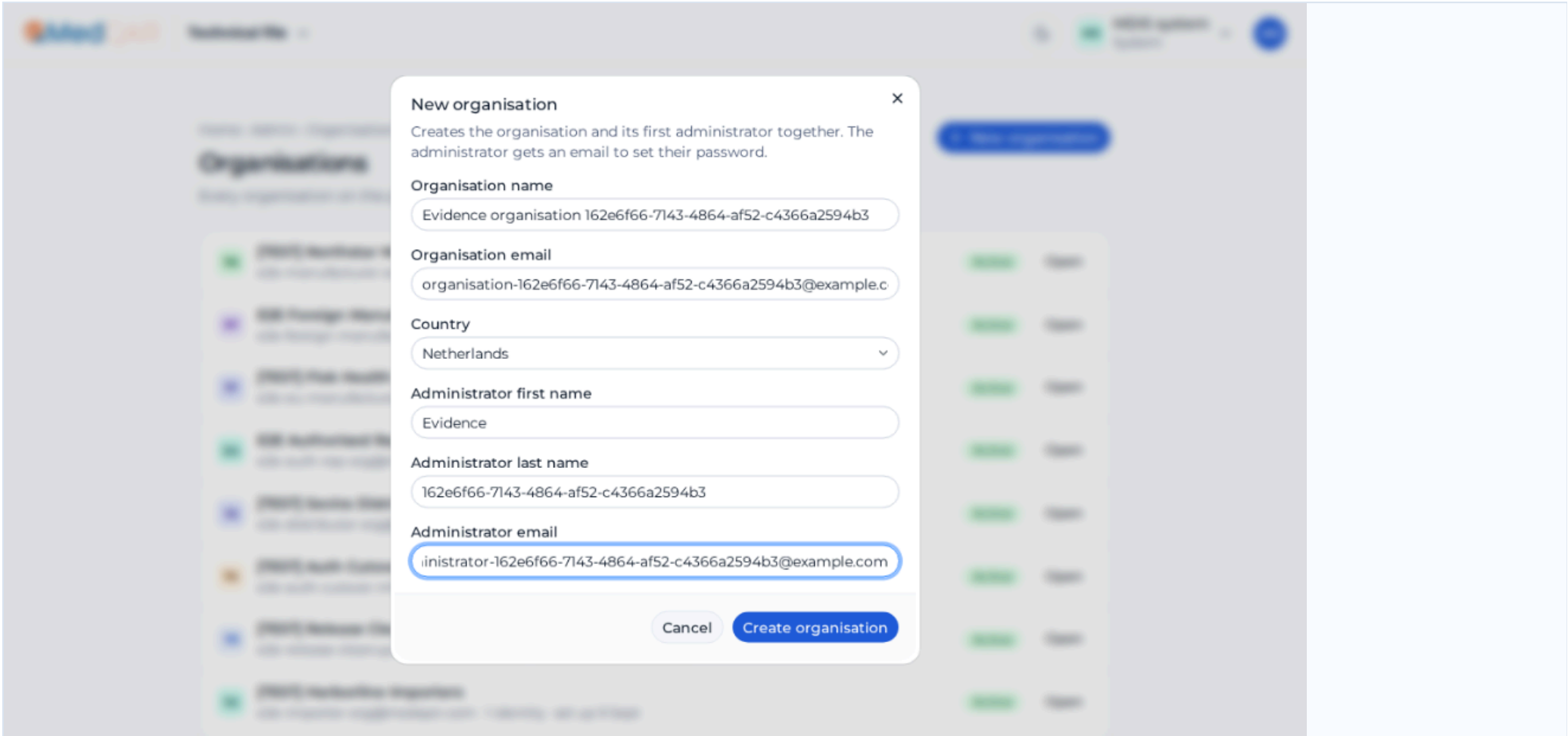
PASS

A system administrator provisions an organisation and its initial administrator

01

EXECUTED GHERKIN STEP

Given a system administrator has filled in a new organisation in ui-v2 PASS



Capture SHA-256: c07f8936ce825749f41c473ef1e71f59091e6796c66a234c89f5a2436a6b0d83

02

EXECUTED GHERKIN STEP

When the administrator submits the new organisation PASS

 Technical file 

  MDIS system  

[Home](#) › [Admin](#) › [Organisations](#)[+ New organisation](#)

Capture SHA-256: 722a7798f097218e4741726cbbf590d47b8be1441362d41d09173ff581e91c81

03

EXECUTED GHERKIN STEP

Then the organisation and initial administrator survive a reload **PASS**

The screenshot shows the MedQAIR web application interface. At the top left is the MedQAIR logo. Next to it is a 'Technical file' dropdown menu. On the top right, there is a refresh icon, a 'MS' status indicator, 'MDIS system' with a dropdown arrow, and a user profile icon labeled 'AD'. The main content area has a breadcrumb trail 'Home > Admin > Users' and a heading 'Users' with the subtitle 'Every user on the platform, across every organisation.' Below this is a search bar with the placeholder text 'Search by name, email or phone'. The search bar contains the text 'administrator-162e6f66-7143-4864-af52-c4366a2594b3@example.com' and has 'Search' and 'Clear' buttons. Below the search bar, a single user entry is displayed in a card. The card has a green 'E1' icon, the title 'Evidence 162e6f66-7143-4864-af52-c4366a2594b3', and the email 'administrator-162e6f66-7143-4864-af52-c4366a2594b3@example.com · Member · Evidence organisatio...'. To the right of the card are two buttons: 'Invited' (orange) and 'Open' (blue).

MedQAIR

Technical file

MS MDIS system System AD

Home > Admin > Users

Users

Every user on the platform, across every organisation.

Search by name, email or phone

administrator-162e6f66-7143-4864-af52-c4366a2594b3@example.com Search Clear

E1 Evidence 162e6f66-7143-4864-af52-c4366a2594b3
administrator-162e6f66-7143-4864-af52-c4366a2594b3@example.com · Member · Evidence organisatio... Invited Open

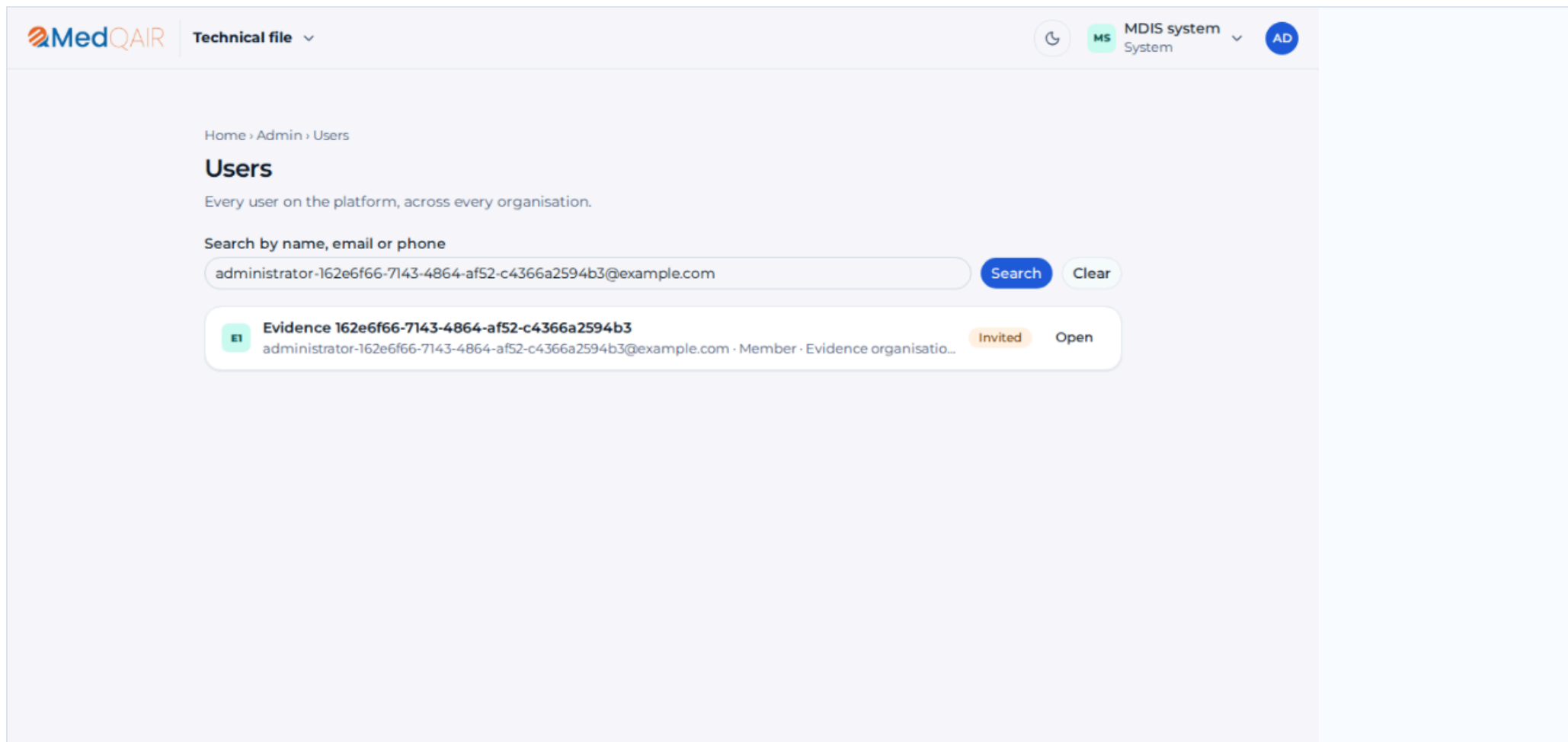
Capture SHA-256: 299e20cec09dc6ec32fd6bca5fbf30f96ae546b159a076a4a09635087bac3d84

04

EXECUTED GHERKIN STEP

And Mailpit receives the initial administrator's activation invitation PASS

No browser change at this step; the activation invitation was asserted through Mailpit metadata



MedQAIR Technical file MDIS system System AD

Home › Admin › Users

Users

Every user on the platform, across every organisation.

Search by name, email or phone

administrator-162e6f66-7143-4864-af52-c4366a2594b3@example.com Search Clear

E1 Evidence 162e6f66-7143-4864-af52-c4366a2594b3
administrator-162e6f66-7143-4864-af52-c4366a2594b3@example.com · Member · Evidence organisatio... Invited Open

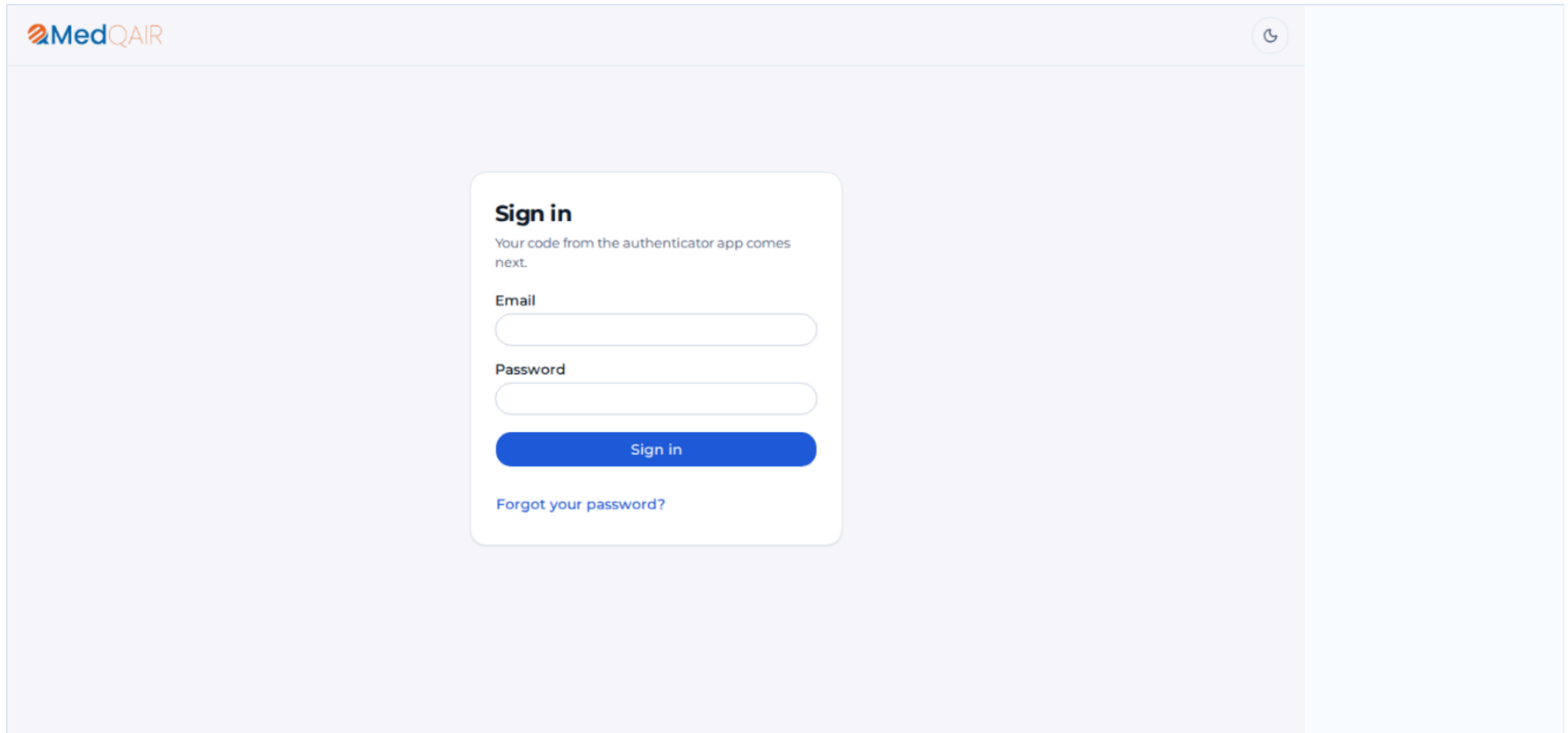
Capture SHA-256: 299e20cec09dc6ec32fd6bca5fbf30f96ae546b159a076a4a09635087bac3d84

A platform admin reads the platform's trail and narrows it to one organisation

01

EXECUTED GHERKIN STEP

Given the redesign sign-in page **PASS**



Capture SHA-256: 953d9a1220a1b501a0ede3a87b7d5516c6552f0e0d727f3b59246c01ef255e3b

02

EXECUTED GHERKIN STEP

When I sign in to the redesign as the platform admin PASS

 Technical file 

 MS MDIS system  AD

Your work

Wednesday 9 September

 **0**
drafts to finish

 **0**
returned for changes

 **0**
waiting on a partner

 **40**
devices, 13 released

Needs you



Your work queue didn't load.
Your work is safe. Try again, or come back in a minute.

Try again

Devices · 40

[All 40 >](#)

PA	PulseView AR Validation ...	Unreleased
AA	AtlasView AR Verification ...	Unreleased
NU	Northgate Unrelated Ten...	Unreleased
AD	AtlasView Ownership Bo...	Unreleased
AD	AtlasView Distributor Gu...	Unreleased
AD	AtlasView Distributor Veri...	Unreleased

Capture SHA-256: 6f83fc842a5b7c489d2a434d822bc79babe7b0d712cd05b9ed04c6becc4c6744

03

EXECUTED GHERKIN STEP

And I open What happened from the operations home PASS

MedQAIR Technical file

MS MDIS system System AD

Operations > What happened

What happened

Everything anyone did on the platform, newest first. Open an organisation to narrow it to their history.

Last 7 days 30 days Everything

Q A person, an organisation, a de

50 entries loaded · every organisation

TODAY

EE E2E releases [Open the release](#)

EU
Manufacturer
submission
prepared

—

Change
2
06:01
-
Change
2
-
[TEST]
Flok
Health

Capture SHA-256: 9cc673d67dd491158991a65a087d1577870e8e66688d98d359c8359e30f87d51

04

EXECUTED GHERKIN STEP

Then the trail lists dated entries, each naming who did what to what **PASS**

The screenshot shows the MedQAIR Technical file interface. The top navigation bar includes the MedQAIR logo, a 'Technical file' dropdown, and user/role indicators (MS, MDIS system, AD). The main content area is titled 'Operations > What happened' and 'What happened', with a subtitle 'Everything anyone did on the platform, newest first. Open an organisation to narrow it to their history.' Below this are filters for 'Last 7 days', '30 days', and 'Everything'. A search bar contains the text 'A person, an organisation, a de'. Below the search bar, it says '50 entries loaded · every organisation'. The main list of entries is titled 'TODAY' and shows a single entry with a yellow icon, 'EE', and text 'E2E releases', 'EU Manufacturer submission prepared', 'Change 2', '06:01', 'Change 2', '[TEST]', 'Flok', and 'Health'. A link 'Open the release' is next to the entry.

Capture SHA-256: 09311b96e45d6e1c47f3b3a2b42ac42ef578a53f50c4e08dfe615750a35c6998

05

EXECUTED GHERKIN STEP

When I narrow the trail to the seeded manufacturer from its record **PASS**

The screenshot displays the MedQAIR Technical file interface. The top navigation bar includes the MedQAIR logo, a 'Technical file' dropdown, and user/role indicators (MS, MDIS system, AD). The main content area shows a breadcrumb trail: 'Operations > Organisations > [TEST] Northstar Medical Imaging > What happened'. The title 'What happened' is followed by a subtitle: '[TEST] Northstar Medical Imaging's trail — the same entries its own administrators see as History.' Below this, there are filters for 'Last 7 days', '30 days', and 'Everything'. A search bar contains the text 'A person, an organisation, a de'. The status '50 entries loaded · [TEST] Northstar Medical Imaging' is shown. A 'TODAY' section highlights an entry with a green 'EM' icon, titled 'E2E identities', with a link 'Open the organisation'. The entry details include 'Manufacturer', 'devices', 'imported', and a timestamp '06:01'.

Capture SHA-256: 23c35595efac5875a4025c41a44c7e732afca41a581559dc11036649d7b275b9

06

EXECUTED GHERKIN STEP

Then every entry shown is about that organisation PASS

 Technical file MDIS system System AD

Operations › Organisations › [TEST] Northstar Medical Imaging › What happened

What happened

[TEST] Northstar Medical Imaging's trail — the same entries its own administrators see as History.

Last 7 days 30 days Everything

50 entries loaded · [TEST] Northstar Medical Imaging

TODAY

EM

E2E identities

Manufacturer

devices

imported

—

[TEST]

Northstar

Medical

Imaging

(Manufacturer)

06:01

.

[TEST]

Northstar

Medical

Imaging

[Open the organisation](#)

Capture SHA-256: 6d4803273f24350075b7463bd1afc9ccc6a90e46974cc22a7d908c4be6adf3f9

Additional screen batch journeys

Focused current-screen journeys retain the same exact scenario identity, tags, assertions, and captures after the primary walkthrough.

features/admin-navigation/screen-admin-navigation.feature · @MODULE:PLATFORM-ADMIN @SR-016 @SR-114

PASS

a platform administrator provisions and finds a run-owned account

01 EXECUTED GHERKIN STEP
Given the platform administrator opens the current Operations workspace PASS

 Technical file

 MS MDIS system System AD

Home > Admin

Operations

What is waiting on a person at MedQAIR, and where to find anything.

+ New organisation

Needs a decision

 **[TEST] Release Cleanup Service · nobody in charge**
No active administrator — nobody there can invite anyone.

Nobody in charge Open

Find

A name, an email address, an SRN or a device

One box for all four registers. A result says which register it came from.

Registers

 **Organisations · 8**
8 active · 0 deactivated · 1 without an administrator Open

 **Users · 17**
17 signed in · 0 deactivated Open

 **Economic operators · 8**
5 manufacturers · 1 authorised representative · 1 distributor · 1 importer

Capture SHA-256: 311fddcb04b89db8cba6252ee160e2d4b83dd6d64ce3295533661438df207f68

02

EXECUTED GHERKIN STEP

Then the Operations registers reflect their persisted API rows **PASS***No visible change at this step; the persisted Operations registers remain visible after reload*

 **Technical file** 

  **MDIS system**  

Home > Admin

Operations

What is waiting on a person at MedQAIR, and where to find anything.

[+ New organisation](#)

Needs a decision

 **[TEST] Release Cleanup Service · nobody in charge**

No active administrator — nobody there can invite anyone.

Nobody in charge [Open](#)

Find

One box for all four registers. A result says which register it came from.

Registers

 **Organisations · 8**

8 active · 0 deactivated · 1 without an administrator

[Open](#)

 **Users · 17**

17 signed in · 0 deactivated

[Open](#)

 **Economic operators · 8**

5 manufacturers · 1 authorised representative · 1 distributor · 1 importer

Capture SHA-256: 311fddcb04b89db8cba6252ee160e2d4b83dd6d64ce3295533661438df207f68

03

EXECUTED GHERKIN STEP

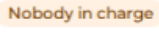
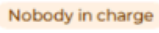
When the platform administrator creates a run-owned organisation **PASS**

 Technical file 

  MDIS system  

[Home](#) > [Admin](#)

Needs a decision

	[TEST] Release Cleanup Service · nobody in charge No active administrator — nobody there can invite anyone.		Open
	E2E Admin Screen 640bfcfa-0875-4d2e-9053-c364572767c2 · nobody in charge No active administrator — nobody there can invite anyone.		Open

Find

One box for all four registers. A result says which register it came from.

Registers

	Organisations · 9 9 active · 0 deactivated · 2 without an administrator	Open
	Users · 17 17 signed in · 0 deactivated	Open

Capture SHA-256: ff2ec9a4f0e2269764bac3dcaaa429f17096e69cbbcec4b6ad64da97a5ae330a

04

EXECUTED GHERKIN STEP

Then the organisation list shows the persisted organisation and administrator **PASS**

 Technical file 

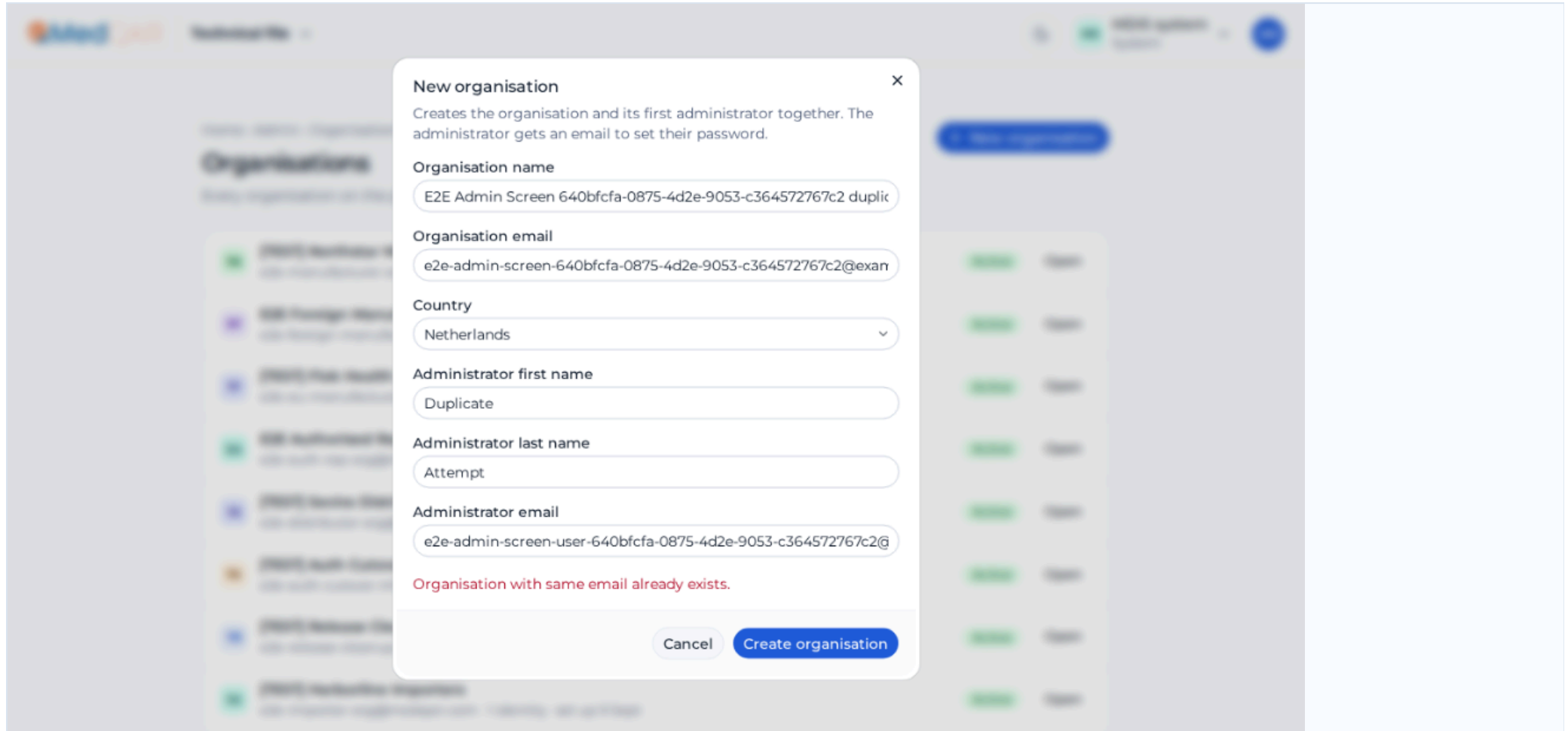
  MDIS system  

[Home](#) › [Admin](#) › [Organisations](#)[+ New organisation](#)

Capture SHA-256: 2198ccafadaf4548b9f1f0d0ce0a6fd25821db4e35ae100f3efecc3da1c56ace

05

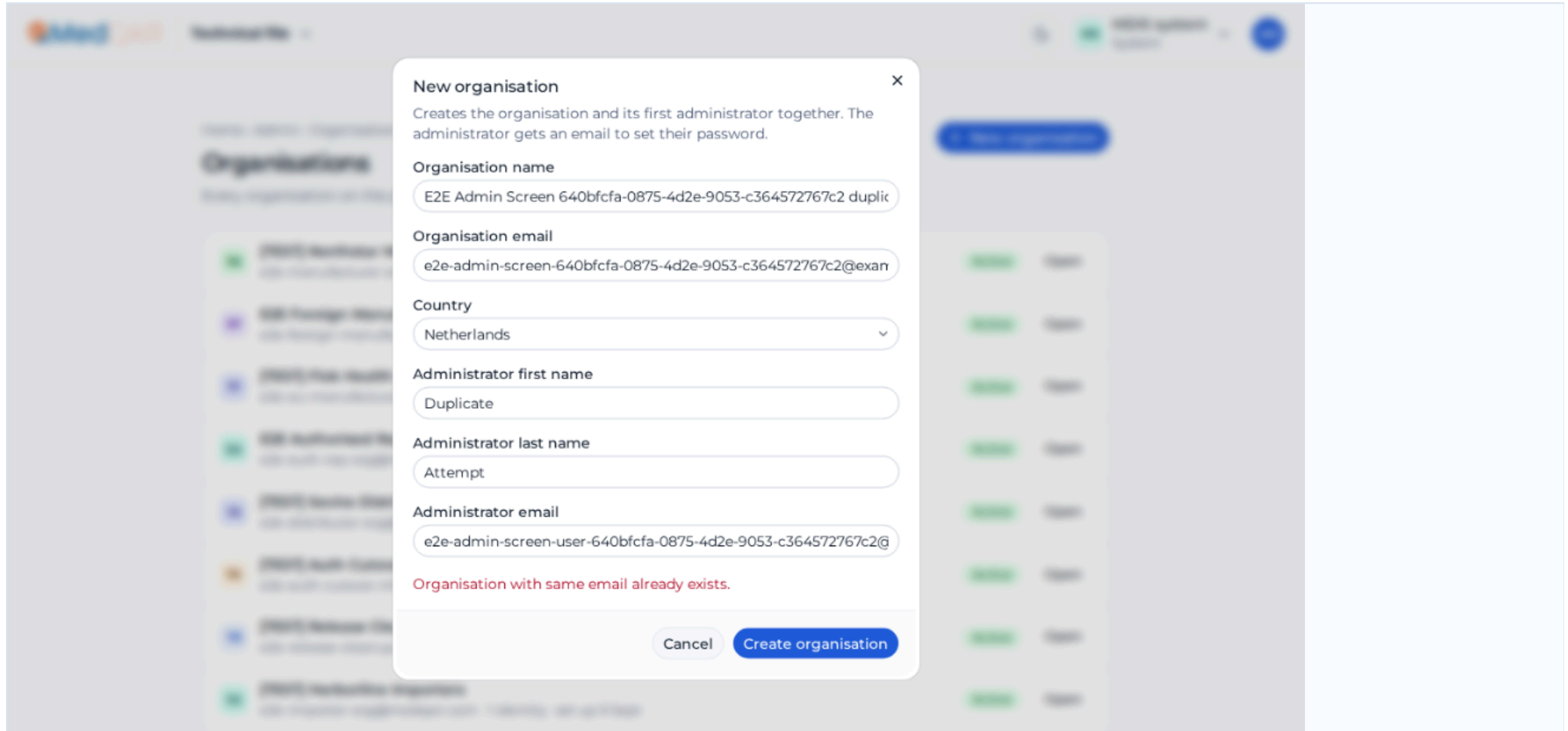
EXECUTED GHERKIN STEP

When the platform administrator retries that organisation email PASS

Capture SHA-256: 5eed35e307ce8efef89624f438cee749095aba159bcffaa16b1f1ca7c51d1da0

06

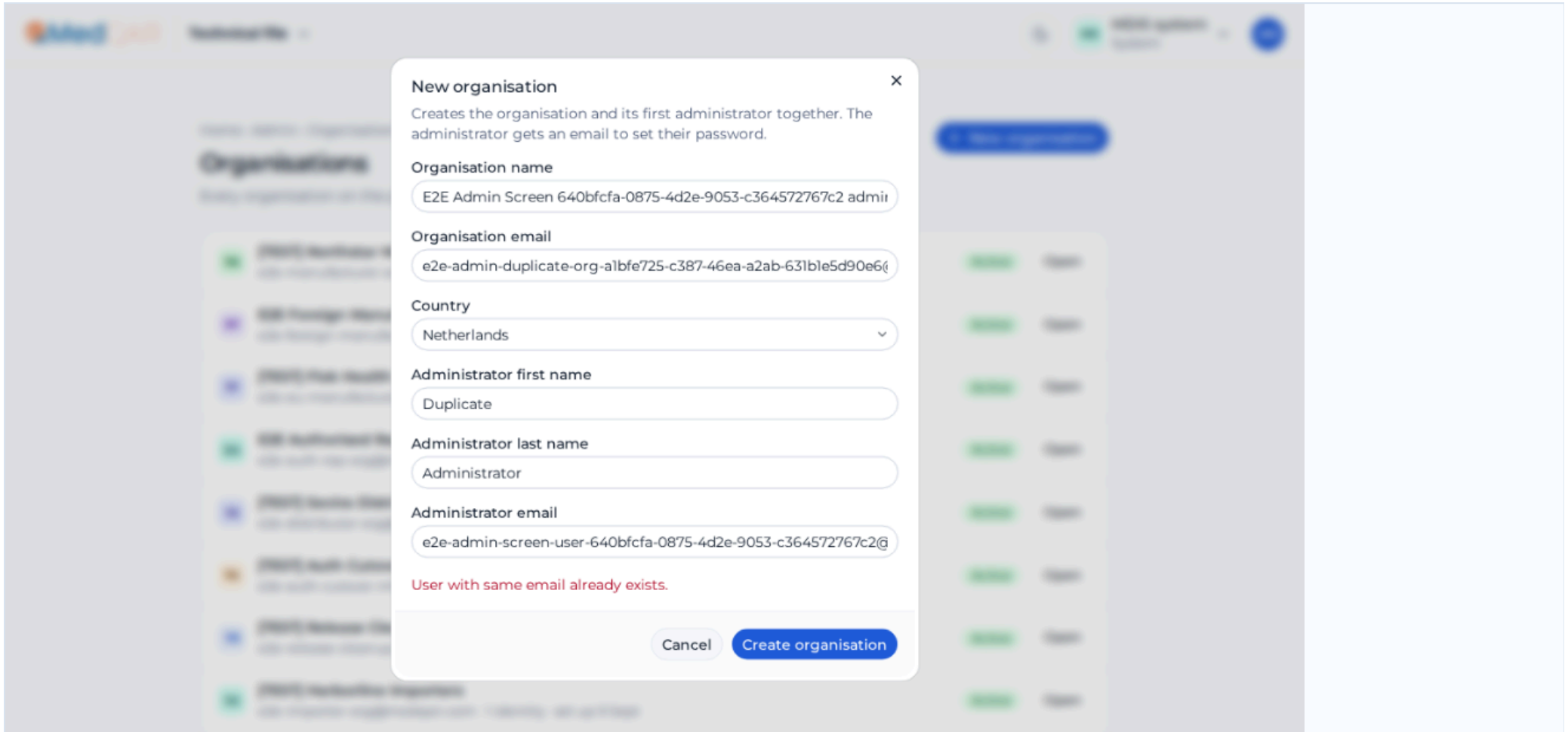
EXECUTED GHERKIN STEP

Then the duplicate organisation is rejected as a named conflict without duplicate rows **PASS**

Capture SHA-256: c315cca506b86276f747a9aafb58be63a737750aef368b869f8603b32ffdea6a

07

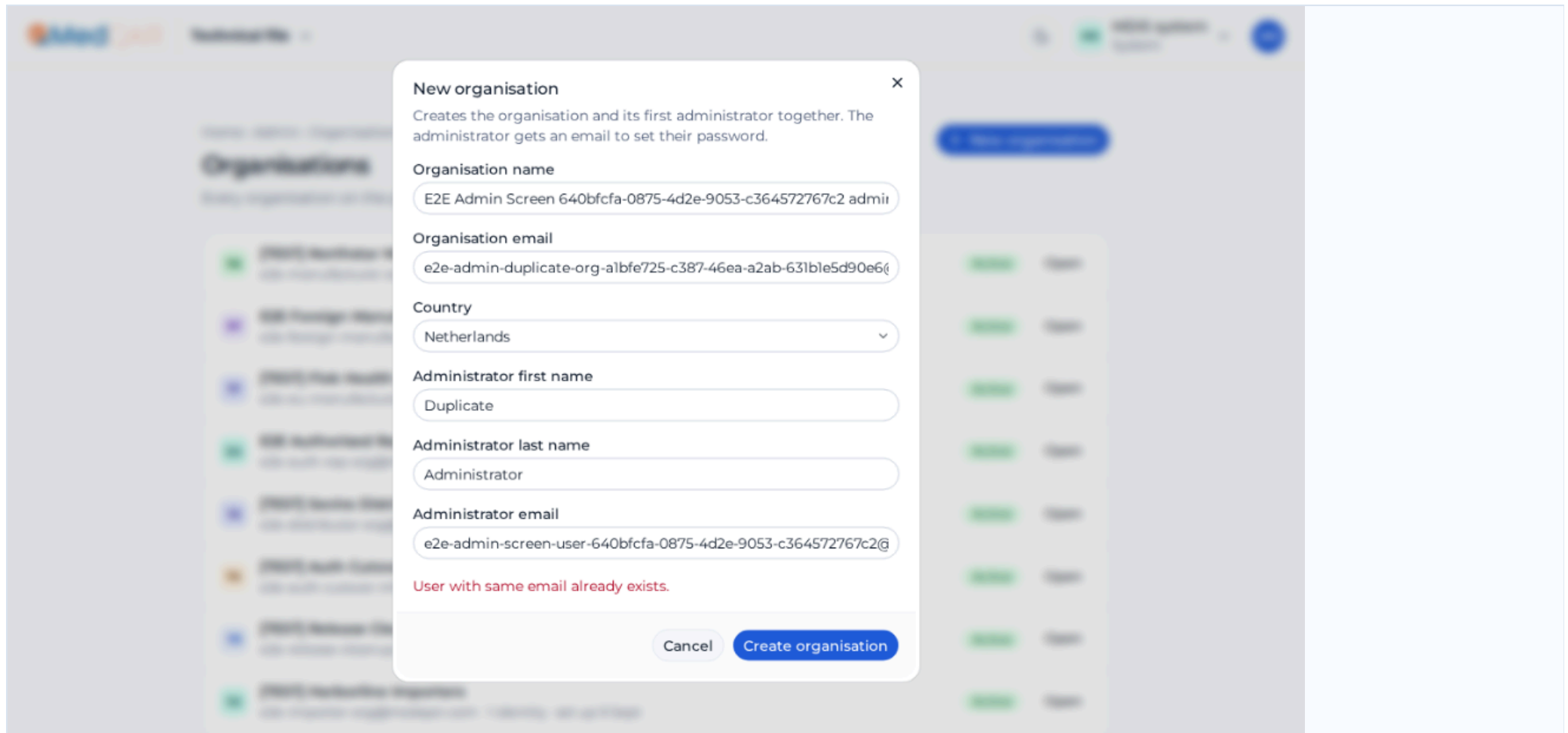
EXECUTED GHERKIN STEP

When the platform administrator retries with that administrator email PASS

Capture SHA-256: 5dc6bc5a58d9a30c60fe7e486f101f1890f7f5ac19f3959917df3d7979a8a280

08

EXECUTED GHERKIN STEP

Then the duplicate administrator is rejected as a named conflict without duplicate rows PASS

Capture SHA-256: 5c04ada14ee03cb94962368b431dfaa6a170ad3e0a5cdc14421843f560e01c83

09

EXECUTED GHERKIN STEP

When the platform administrator searches for the run-owned administrator PASS

MedQAIR Technical file ▾

Home › Admin › Users

Users

Every user on the platform, across every organisation.

Search by name, email or phone

e2e-admin-screen-user-640bfcfa-0875-4d2e-9053-c364572767c2@example.com Search Clear

EA **Evidence Admin-640bfcfa-0875-4d2e-9053-c364572767c2**
e2e-admin-screen-user-640bfcfa-0875-4d2e-9053-c364572767c2@example.com · Member · E2E Admi... Invited Open

Capture SHA-256: a1516e4479b3aaf71bdcf1dc28717b1374b022a73721b5fd6aac0f4e4339dcdb

10

EXECUTED GHERKIN STEP

Then the user list shows only the exact run-owned account PASS

No visible change at this step; the exact run-owned account remains visibly listed

The screenshot shows the MedQAIR interface. At the top, there's a header with the MedQAIR logo, a 'Technical file' dropdown, and system status indicators for 'MS' and 'MDIS system' (System) with an 'AD' button. The main content area has a breadcrumb 'Home > Admin > Users' and a title 'Users' with the subtitle 'Every user on the platform, across every organisation.' Below this is a search bar with the placeholder 'Search by name, email or phone'. The search bar contains the text 'e2e-admin-screen-user-640bfcfa-0875-4d2e-9053-c364572767c2@example.com' and has 'Search' and 'Clear' buttons. A search result is displayed in a card format, showing a user icon with 'EA', the name 'Evidence Admin-640bfcfa-0875-4d2e-9053-c364572767c2', the email 'e2e-admin-screen-user-640bfcfa-0875-4d2e-9053-c364572767c2@example.com', the role 'Member · E2E Admi...', and status buttons 'Invited' and 'Open'.

Home > Admin > Users

Users

Every user on the platform, across every organisation.

Search by name, email or phone

e2e-admin-screen-user-640bfcfa-0875-4d2e-9053-c364572767c2@example.com Search Clear

EA

Evidence Admin-640bfcfa-0875-4d2e-9053-c364572767c2
e2e-admin-screen-user-640bfcfa-0875-4d2e-9053-c364572767c2@example.com · Member · E2E Admi...

Invited Open

Capture SHA-256: a1516e4479b3aaf71bdcf1dc28717b1374b022a73721b5fd6aac0f4e4339dcdb

11

EXECUTED GHERKIN STEP

When the platform administrator checks empty, name, email and phone user searches PASS

 Technical file 

  MDIS system  

[Home](#) > [Admin](#) > [Users](#)

Users

Every user on the platform, across every organisation.

Search by name, email or phone

Search

Clear

 **Evidence Admin-640bfcfa-0875-4d2e-9053-c364572767c2**

e2e-admin-screen-user-640bfcfa-0875-4d2e-9053-c364572767c2@example.com · Member · E2E Admi...

Invited

Open

Capture SHA-256: e268a818f12c59c8a3c084f05ceb6f6131c2942726a5fddcdb07cc7a2b54459b

12

EXECUTED GHERKIN STEP

When the platform administrator opens that user **PASS**

The screenshot displays the MedQAIR user management interface. At the top, the MedQAIR logo is on the left, and a 'Technical file' dropdown menu is in the center. On the right, there are icons for a refresh button, 'MS' (Microsoft), 'MDIS system System' (with a dropdown arrow), and 'AD' (Active Directory). Below the header, a breadcrumb trail reads 'Home > Admin > Users > User'. The main content area shows the user details for 'Evidence Admin-640bfcfa-0875-4d2e-9053-c364572767c2', with an 'Active' status tag. Below the name is the email address 'e2e-admin-screen-user-640bfcfa-0875-4d2e-9053-c364572767c2@example.com'. A table-like structure displays the following information:

User type	Phone
Member	—
Organisation	Member since
E2E Admin Screen 640bfcfa-0875-4d2e-9053-c364572767c2	9/9/2026
Role	Multi-factor authentication
Organisation admin	MFA not enabled

Below the table, there is a button labeled 'Send password reset email'.

Capture SHA-256: d1d1c260cb6643b8be03c5d280a597445b4c8bcb9e63396a5f644731847efad

13

EXECUTED GHERKIN STEP

Then the user detail shows the persisted identity and role facts **PASS**

No visible change at this step; the persisted identity and role facts remain visible

The screenshot displays the MedQAIR user management interface. The top navigation bar includes the MedQAIR logo, a 'Technical file' dropdown, and system status indicators for 'MS' (MDIS system) and 'AD'. The breadcrumb trail shows 'Home > Admin > Users > User'. The user details for 'Evidence Admin-640bfcfa-0875-4d2e-9053-c364572767c2' are shown, with an 'Active' status. The email address is 'e2e-admin-screen-user-640bfcfa-0875-4d2e-9053-c364572767c2@example.com'. A table lists user attributes: User type (Member), Organisation (E2E Admin Screen 640bfcfa-0875-4d2e-9053-c364572767c2), Role (Organisation admin), Phone (—), Member since (9/9/2026), and Multi-factor authentication (MFA not enabled). A 'Send password reset email' button is located below the table.

User type	Phone
Member	—
Organisation	Member since
E2E Admin Screen 640bfcfa-0875-4d2e-9053-c364572767c2	9/9/2026
Role	Multi-factor authentication
Organisation admin	MFA not enabled

Send password reset email

Capture SHA-256: d1d1c260cb6643b8be03c5d280a597445b4c8bcb9e63396a5f644731847efad

14

EXECUTED GHERKIN STEP

When the platform administrator confirms a password reset for that user PASS

The screenshot displays the MedQAIR user management interface. At the top, the MedQAIR logo is on the left, and 'Technical file' with a dropdown arrow is in the center. On the right, there are icons for a refresh button, 'MS' (MDIS system), and 'AD' (System). Below the header, a breadcrumb trail reads 'Home > Admin > Users > User'. The main content area features a user profile for 'Evidence Admin-640bfcfa-0875-4d2e-9053-c364572767c2' with an 'Active' status. Below the name is the email address 'e2e-admin-screen-user-640bfcfa-0875-4d2e-9053-c364572767c2@example.com'. A table-like structure displays user details: 'User type' is 'Member', 'Phone' is '—', 'Organisation' is 'E2E Admin Screen 640bfcfa-0875-4d2e-9053-c364572767c2', 'Member since' is '9/9/2026', 'Role' is 'Organisation admin', and 'Multi-factor authentication' is 'MFA not enabled'. Below this, there is a 'Send password reset email' button. A green notification box in the bottom right corner shows a checkmark and the message: 'Password reset email sent to e2e-admin-screen-user-640bfcfa-0875-4d2e-9053-c364572767c2@example.com'.

Home > Admin > Users > User

Evidence Admin-640bfcfa-0875-4d2e-9053-c364572767c2 Active

e2e-admin-screen-user-640bfcfa-0875-4d2e-9053-c364572767c2@example.com

User type	Phone
Member	—
Organisation	Member since
E2E Admin Screen 640bfcfa-0875-4d2e-9053-c364572767c2	9/9/2026
Role	Multi-factor authentication
Organisation admin	MFA not enabled

[Send password reset email](#)

✕

✓ Password reset email sent to e2e-admin-screen-user-640bfcfa-0875-4d2e-9053-c364572767c2@example.com

Capture SHA-256: a523d4602ec38e241064355c3fd703969895d84cf38c8f96f59398443b07abfd

15

EXECUTED GHERKIN STEP

Then the password reset succeeds through the real API and is reported by name PASS*No visible change at this step; the named password-reset confirmation remains visible*

The screenshot displays the MedQAIR user management interface. At the top, there is a header with the MedQAIR logo, a 'Technical file' dropdown, and system status indicators for 'MS' (MDIS system) and 'AD'. The breadcrumb trail indicates the current location: 'Home > Admin > Users > User'. The user profile for 'Evidence Admin-640bfcfa-0875-4d2e-9053-c364572767c2' is shown, with a status of 'Active'. Below the profile, a table lists user details: User type (Member), Organisation (E2E Admin Screen 640bfcfa-0875-4d2e-9053-c364572767c2), Role (Organisation admin), Phone (—), Member since (9/9/2026), and Multi-factor authentication (MFA not enabled). A 'Send password reset email' button is visible. A green confirmation message at the bottom right states: 'Password reset email sent to e2e-admin-screen-user-640bfcfa-0875-4d2e-9053-c364572767c2@example.com'.

Home > Admin > Users > User

Evidence Admin-640bfcfa-0875-4d2e-9053-c364572767c2 Active

e2e-admin-screen-user-640bfcfa-0875-4d2e-9053-c364572767c2@example.com

User type	Phone
Member	—
Organisation	Member since
E2E Admin Screen 640bfcfa-0875-4d2e-9053-c364572767c2	9/9/2026
Role	Multi-factor authentication
Organisation admin	MFA not enabled

[Send password reset email](#)

✕

✓ Password reset email sent to e2e-admin-screen-user-640bfcfa-0875-4d2e-9053-c364572767c2@example.com

Capture SHA-256: a523d4602ec38e241064355c3fd703969895d84cf38c8f96f59398443b07abfd

16

EXECUTED GHERKIN STEP

When the platform administrator opens the account navigation menu **PASS**

The screenshot displays the MedQAIR user management interface. At the top, the MedQAIR logo is on the left, and a 'Technical file' dropdown menu is in the center. On the right, there is a user profile icon, a 'MS' badge, and a 'MDIS system' dropdown menu. Below the 'MDIS system' dropdown, a navigation menu is open, listing various options under 'ORGANISATION' and 'PLATFORM ADMIN'. The main content area shows the profile of a user named 'Evidence Admin-640bfcfa-0875-4d2e-9053-c364572767c2', who is 'Active'. The user's email is 'e2e-admin-screen-user-640bfcfa-0875-4d2e-9053-c364572767c2@example.com'. The profile details include: User type (Member), Organisation (E2E Admin Screen 640bfcfa-0875-4d2e-9053-c364572767c2), Role (Organisation admin), Phone (—), Member since (9/9/2026), and Multi-factor authentication (MFA not enabled). A 'Send password reset email' button is located below the profile details. A green notification box at the bottom right states: 'Password reset email sent to e2e-admin-screen-user-640bfcfa-0875-4d2e-9053-c364572767c2@example.com'.

MedQAIR Technical file

Home > Admin > Users > User

Evidence Admin-640bfcfa-0875-4d2e-9053-c364572767c2 Active

e2e-admin-screen-user-640bfcfa-0875-4d2e-9053-c364572767c2@example.com

User type	Phone
Member	—
Organisation	Member since
E2E Admin Screen 640bfcfa-0875-4d2e-9053-c364572767c2	9/9/2026
Role	Multi-factor authentication
Organisation admin	MFA not enabled

Send password reset email

ORGANISATION

- Organisation hub

PLATFORM ADMIN

- Operations
- Organisations — all platform
- Users — all organisations
- Claims waiting
- Guided tour · off
- Privacy policy
- Sign out

Password reset email sent to e2e-admin-screen-user-640bfcfa-0875-4d2e-9053-c364572767c2@example.com

Capture SHA-256: ee0b1bc23f2f4725071be3d1fe22e8031608900a7efdac1c52d62167216358f5

17

EXECUTED GHERKIN STEP

Then the platform admin destinations and privacy policy are discoverable PASS

The screenshot shows the MedQAIR Admin interface. The top navigation bar includes the MedQAIR logo, a 'Technical file' dropdown, and a user profile 'MS MDIS system System' with a dropdown arrow. A dropdown menu is open, displaying the following options:

- ORGANISATION
 - Organisation hub
- PLATFORM ADMIN
 - Operations
 - Organisations — all platform
 - Users — all organisations
 - Claims waiting
 - Guided tour · off
 - Privacy policy
 - Sign out

The main content area is titled 'Operations' and includes a breadcrumb 'Home > Admin'. Below the title is a description: 'What is waiting on a person at MedQAIR, and where to find anything.' There are three main sections:

- Needs a decision**: A card titled '[TEST] Release Cleanup Service · nobody in charge' with a status 'Nobody in charge'.
- Find**: A search bar with the placeholder 'A name, an email address, an SRN or a device' and a note 'One box for all four registers. A result says which register it came from.'
- Registers**: A table listing various registers with their counts and status.

Register	Count	Status	Action
Organisations	9	9 active · 0 deactivated · 1 without an administrator	Open
Users	19	17 signed in · 2 invited and never signed in · 0 deactivated	Open
Economic operators	8	5 manufacturers · 1 authorised representative · 1 distributor · 1 importer	

Capture SHA-256: a5f26aed5198d9f9e6d227aacf432fd3799be110546e14849cd0061fceca0124

 Technical file 

  MDIS system 
System 

 **Your documents stay yours**

Documents you upload are visible only under the sharing rules your organisation sets. MDIS never shares them more widely on its own.

 **Account data**

MDIS stores your name, work email address and role. They are used for access control and to attribute entries in the audit log — nothing else.

 **Audit trail**

Regulated actions are recorded with your name and the date, and kept for the retention period your organisation is required to observe.

 **Public eIFU**

Published instructions for use are public by design. No personal data is published with them.

Capture SHA-256: adf9cf75a0d1e26c704d19d01f9cc7fcdc8d118eda4656ac1ee23d569f4c1140

19

EXECUTED GHERKIN STEP

Then the privacy summary is complete and the account menu has no sidebar substitute PASS*No visible change at this step; the complete privacy summary remains visible*

 Technical file 

  MDIS system  

Privacy policy

How MDIS handles data — the short form.

 **Your documents stay yours**

Documents you upload are visible only under the sharing rules your organisation sets. MDIS never shares them more widely on its own.

 **Account data**

MDIS stores your name, work email address and role. They are used for access control and to attribute entries in the audit log — nothing else.

 **Audit trail**

Regulated actions are recorded with your name and the date, and kept for the retention period your organisation is required to observe.

 **Public eIFU**

Published instructions for use are public by design. No personal data is published with them.

This is a summary, not the policy itself. The full privacy policy is available from your organisation.

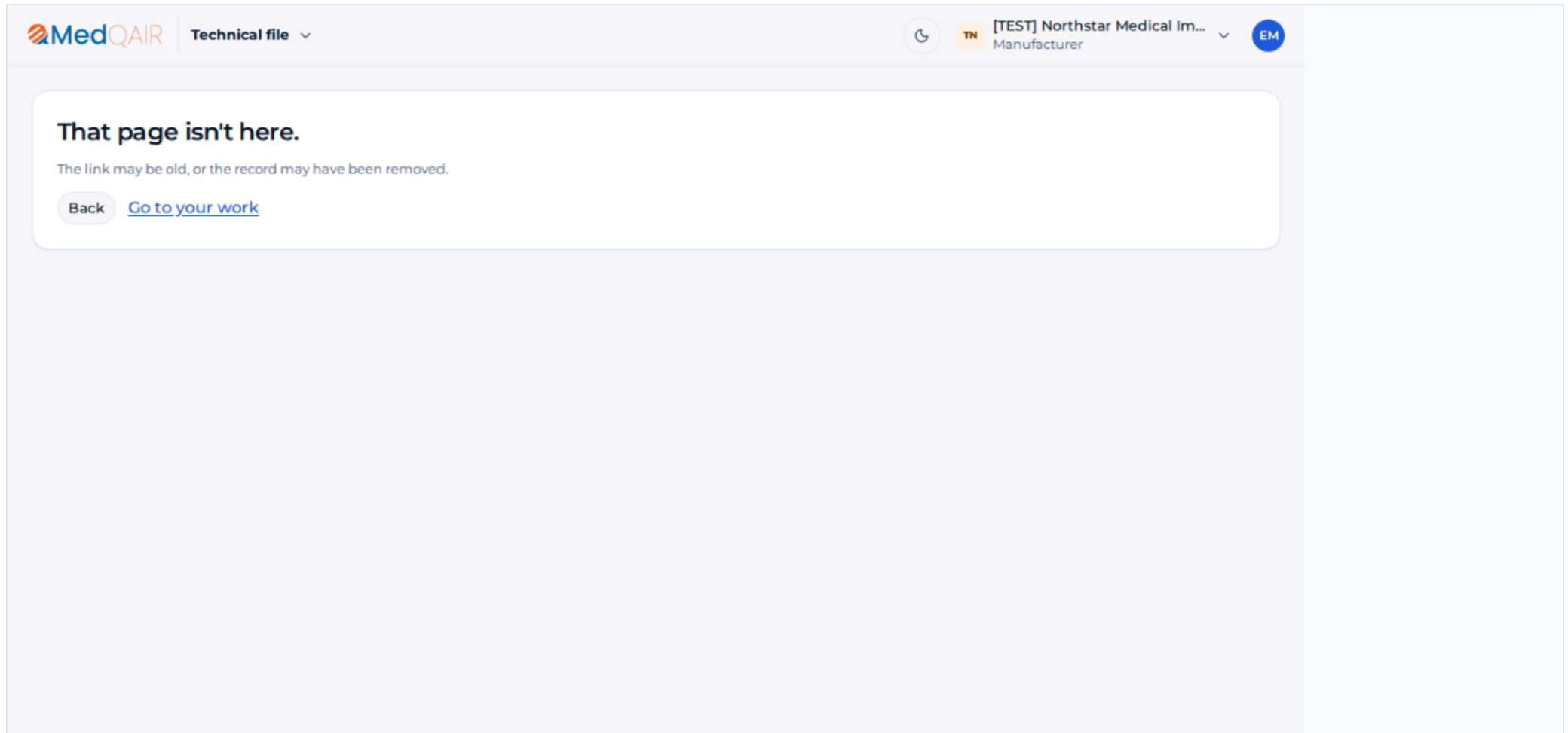
Capture SHA-256: adf9cf75a0d1e26c704d19d01f9cc7fcdc8d118eda4656ac1ee23d569f4c1140

an organisation user cannot discover the platform admin workspace

01

EXECUTED GHERKIN STEP

Given an organisation user opens the platform admin entry point **PASS**



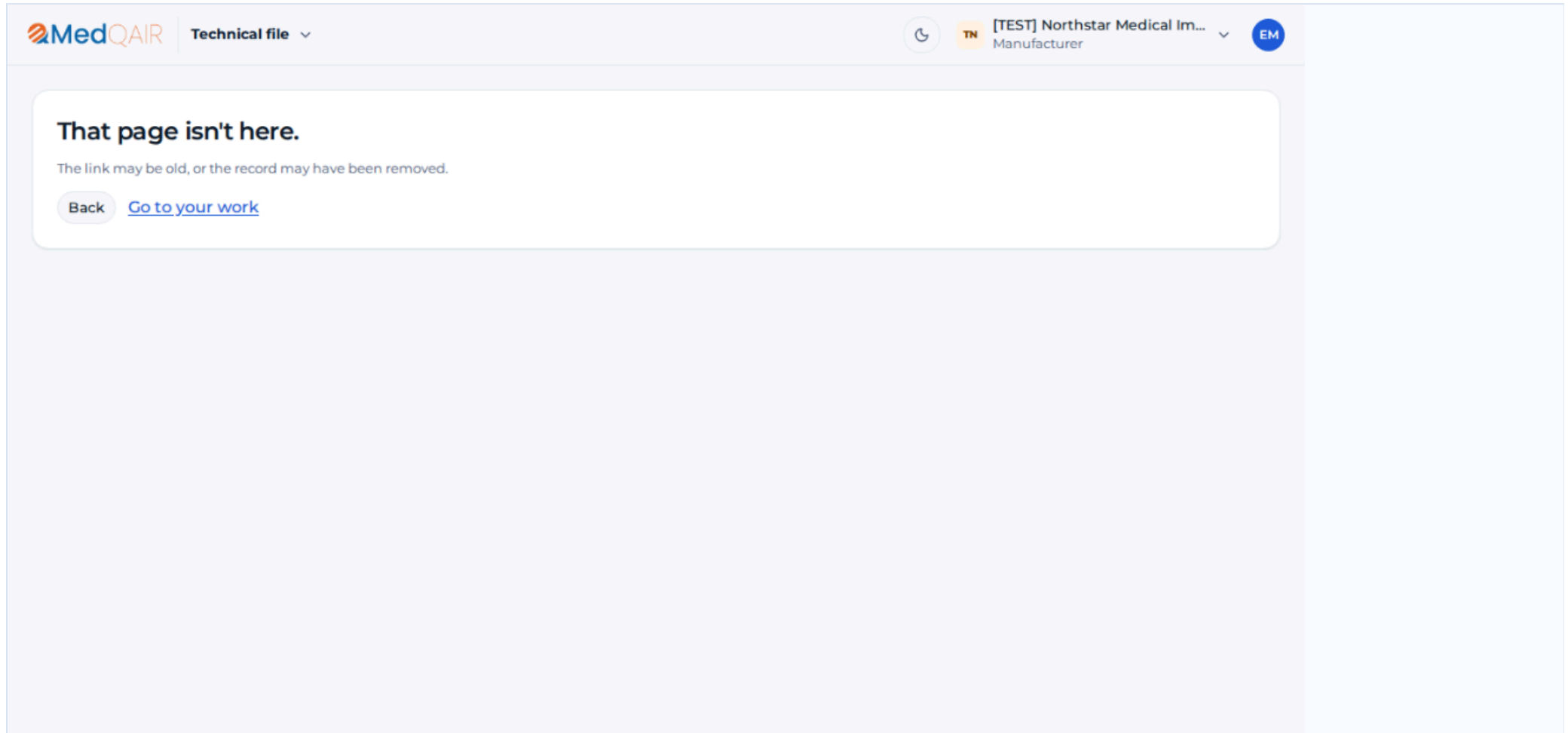
Capture SHA-256: 99d5d062d612eedfbc804191bd341f2b259a44461f1d7761925543ae020a4b67

02

EXECUTED GHERKIN STEP

Then the platform admin entry point is the ordinary not-found page **PASS**

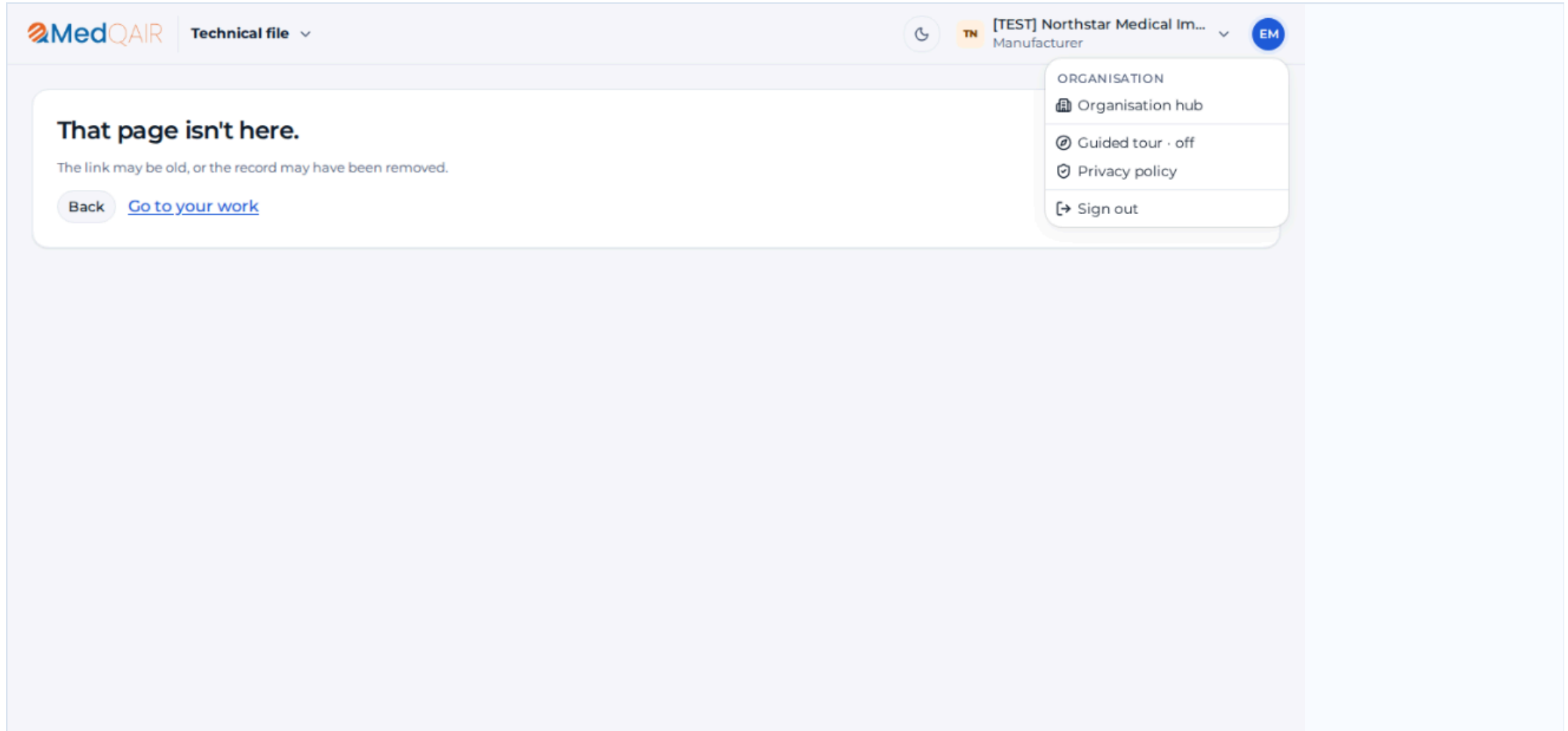
No visible change at this step; the disclosure-safe not-found page remains visible



Capture SHA-256: 99d5d062d612eedfbc804191bd341f2b259a44461f1d7761925543ae020a4b67

03

EXECUTED GHERKIN STEP

And the organisation user's account menu has no platform admin section **PASS**

Capture SHA-256: 8a70ec33b7c26a3b511baee612ba7f6066a80badd78afcd6ba0c2c758ff2beee

an organisation administrator reads facts with their provenance

01 EXECUTED GHERKIN STEP
Given an organisation administrator opens the current organisation facts PASS

MedQAIR

Technical file

TN

[TEST] Northstar Medical Im...

Manufacturer

EM

← Home

Organisation

Bulk import

Organisation facts

Users5

Partners11

RELEASES

Published instructions

Release checks

Release history

History as administrator

ACCOUNT

Sign-in and MFA

Organisation facts

What partners and the public directory see. Edits are recorded; they never touch a release.

Update from EUDAMED

Edit

LEGAL NAME

[TEST] Northstar Medical Imaging

ADDRESS

Not recorded

SRN

US-MF-000000001 · EU MDR · from EUDAMED, read-only here

PRRC

E2E PRRC · EU MDR, Article 15 · a person from Users

BILLING CONTACT

e2e-manufacturer-org@medqair.com

Last edited 9 Sept 2026 by System

Capture SHA-256: 04a90a01c120a54e428ef881c08d5b365fd4e653e3132e80a6d27d50bd234f4d

02

EXECUTED GHERKIN STEP

Then the organisation facts match the persisted projection and provenance notes PASS

No visible change at this step; asserted through the API read

 **Technical file** 

  **[TEST] Northstar Medical Im...**  

 Home

Organisation

 Bulk import

 **Organisation facts**

 Users 5

 Partners 11

RELEASES

 Published instructions

 Release checks

 Release history

 History as administrator

ACCOUNT

 Sign-in and MFA

Organisation facts

What partners and the public directory see. Edits are recorded; they never touch a release.

Update from EUDAMED

 Edit

LEGAL NAME
[TEST] Northstar Medical Imaging

ADDRESS
Not recorded

SRN
US-MF-000000001 · EU MDR · from EUDAMED, read-only here

PRRC
E2E PRRC · EU MDR, Article 15 - a person from Users

BILLING CONTACT
e2e-manufacturer-org@medqair.com

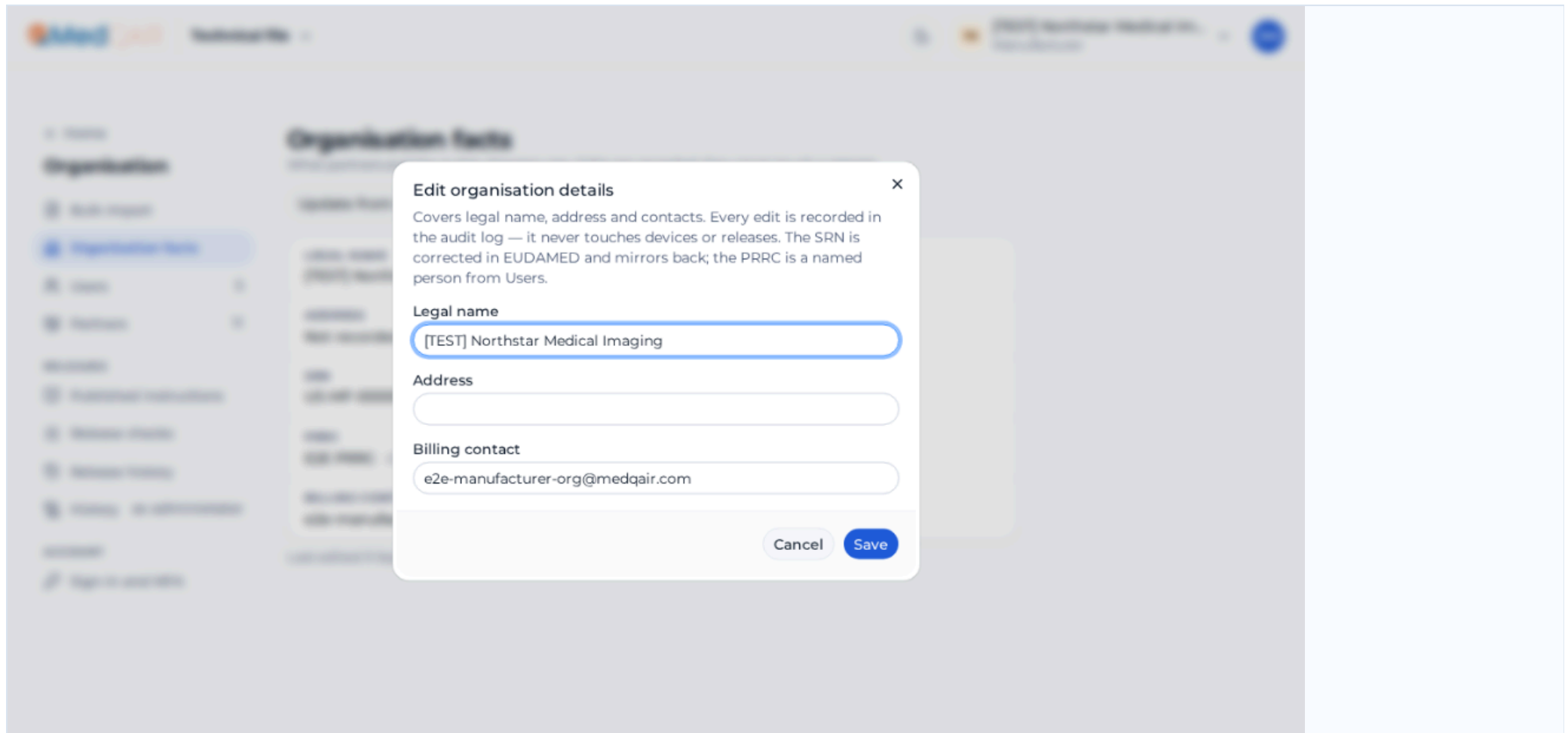
Last edited 9 Sept 2026 by System

Capture SHA-256: 04a90a01c120a54e428ef881c08d5b365fd4e653e3132e80a6d27d50bd234f4d

MDIS walkthrough · 192 / 418

03

EXECUTED GHERKIN STEP

When the organisation administrator opens Edit organisation details PASS

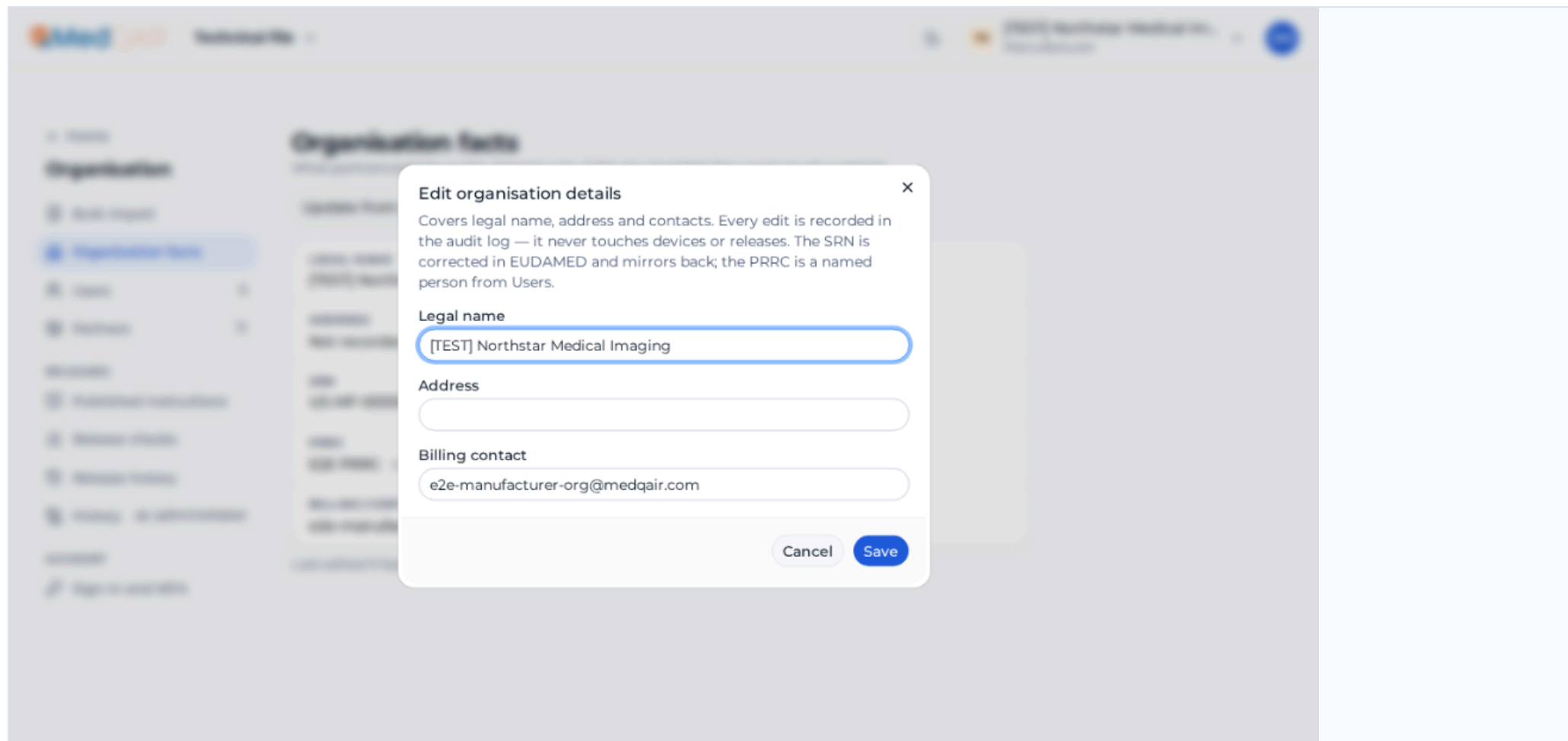
Capture SHA-256: ac6db47e33b3391eedcacac3cef106989954fddc47986a8ca298d0d53dd6f2a0

04

EXECUTED GHERKIN STEP

Then only legal name, address and billing contact are editable PASS

No visible change at this step; the open dialog's editable fields and restrictions were checked.



Capture SHA-256: ac6db47e33b3391eedcacac3cef106989954fddc47986a8ca298d0d53dd6f2a0

05

EXECUTED GHERKIN STEP

When the organisation administrator cancels the organisation facts edit PASS

 Technical file 

  [TEST] Northstar Medical Im...  

 Home

Organisation

 Bulk import

 **Organisation facts**

 Users 5

 Partners 11

RELEASES

 Published instructions

 Release checks

 Release history

 History as administrator

ACCOUNT

 Sign-in and MFA

Organisation facts

What partners and the public directory see. Edits are recorded; they never touch a release.

Update from EUDAMED

 Edit

LEGAL NAME

[TEST] Northstar Medical Imaging

ADDRESS

Not recorded

SRN

US-MF-000000001 · EU MDR · from EUDAMED, read-only here

PRRC

E2E PRRC · EU MDR, Article 15 · a person from Users

BILLING CONTACT

e2e-manufacturer-org@medqair.com

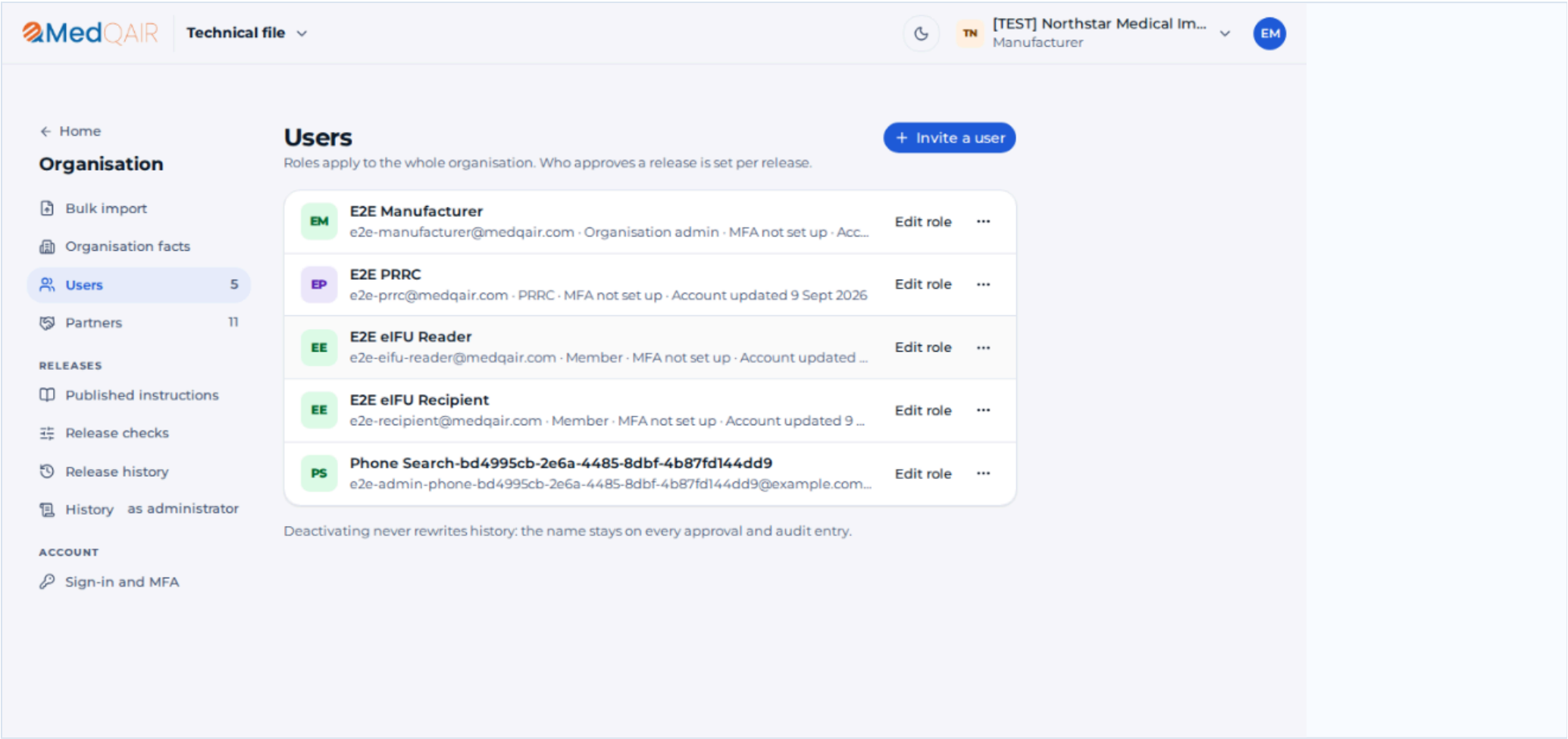
Last edited 9 Sept 2026 by System

Capture SHA-256: 04a90a01c120a54e428ef881c08d5b365fd4e653e3132e80a6d27d50bd234f4d

an organisation administrator stages and revokes a run-owned invitation

01 EXECUTED GHERKIN STEP

Given an organisation administrator opens the current organisation users PASS



Capture SHA-256: d86f9b1b3467a1250a90a19b974443fa3ee69bed85607e9bb268625a3ad863c9

02

EXECUTED GHERKIN STEP

When the organisation administrator invites a run-owned member PASS

MedQAIR Technical file ↕ ⌂ TN [TEST] Northstar Medical Im... ↕ EM

[← Home](#)

Organisation

- [Bulk import](#)
- [Organisation facts](#)
- [Users](#) 6**
- [Partners 11](#)

RELEASES

- [Published instructions](#)
- [Release checks](#)
- [Release history](#)
- [History as administrator](#)

ACCOUNT

- [Sign-in and MFA](#)

Users

Roles apply to the whole organisation. Who approves a release is set per release.

[+ Invite a user](#)

EM	E2E Manufacturer e2e-manufacturer@medqair.com · Organisation admin · MFA not set up · Acc...	Edit role	...
EP	E2E PRRC e2e-prrc@medqair.com · PRRC · MFA not set up · Account updated 9 Sept 2026	Edit role	...
EE	E2E eIFU Reader e2e-eifu-reader@medqair.com · Member · MFA not set up · Account updated ...	Edit role	...
EE	E2E eIFU Recipient e2e-recipient@medqair.com · Member · MFA not set up · Account updated 9 ...	Edit role	...
PS	Phone Search-bd4995cb-2e6a-4485-8dbf-4b87fd144dd9 e2e-admin-phone-bd4995cb-2e6a-4485-8dbf-4b87fd144dd9@example.com...	Edit role	...
ES	e2e-screen-admin-0ac5a2c9-28d2-4250-ae79-89769f834d01... Member · Invitation pending · Invited 9 Sept 2026 · expires 16 Sept 2...	Invited	Resend ...

Deactivating never rewrites history; the name stays on every approval and audit entry.

Capture SHA-256: 39dc3a8dcc458fdb30acf3e57db841bef0415c6e07de68f5c976718dd6ae88e9

03 EXECUTED GHERKIN STEP

Then the pending member row shows its role and fourteen-day expiry PASS

 Technical file 

  [TEST] Northstar Medical Im...  

 Home

Organisation

 Bulk import

 Organisation facts

 **Users** 6

 Partners 11

RELEASES

 Published instructions

 Release checks

 Release history

 History as administrator

ACCOUNT

 Sign-in and MFA

Users

Roles apply to the whole organisation. Who approves a release is set per release.

 **E2E Manufacturer**
e2e-manufacturer@medqair.com · Organisation admin · MFA not set up · Acc...

 **E2E PRRC**
e2e-prrc@medqair.com · PRRC · MFA not set up · Account updated 9 Sept 2026

 **E2E eIFU Reader**
e2e-eifu-reader@medqair.com · Member · MFA not set up · Account updated ...

 **E2E eIFU Recipient**
e2e-recipient@medqair.com · Member · MFA not set up · Account updated 9 ...

 **Phone Search-bd4995cb-2e6a-4485-8dbf-4b87fd144dd9**
e2e-admin-phone-bd4995cb-2e6a-4485-8dbf-4b87fd144dd9@example.com...

 **e2e-screen-admin-0ac5a2c9-28d2-4250-ae79-89769f834d01...**
Member · Invitation pending · Invited 9 Sept 2026 · expires 16 Sept 2...

Edit role

...

Edit role

...

Edit role

...

Edit role

...

Edit role

...

Invited

Resend

...

Deactivating never rewrites history; the name stays on every approval and audit entry.

+ Invite a user

Capture SHA-256: 0318626c6d8e0c8a447f4e57e89ad0019d4f45d9b228b0a75c126f827d0b759b

04

EXECUTED GHERKIN STEP

When the organisation administrator resends that invitation PASS

The screenshot displays the MedQAIR interface. At the top, the MedQAIR logo is on the left, and the user profile '[TEST] Northstar Medical Im...' is on the right. The main navigation sidebar on the left includes 'Organisation', 'Partners', 'RELEASES', and 'ACCOUNT'. The 'Users' section is active, showing a list of users. The user 'e2e-screen-admin-0ac5a2c9-28d2-4250-ae79-89769f834d01...' is highlighted, and the 'Resend' button is circled in blue.

User ID	Role	Status	Action
e2e-manufacturer@medqair.com	E2E Manufacturer	Active	Edit role
e2e-prrc@medqair.com	E2E PRRC	Active	Edit role
e2e-eifu-reader@medqair.com	E2E eIFU Reader	Active	Edit role
e2e-recipient@medqair.com	E2E eIFU Recipient	Active	Edit role
e2e-admin-phone-bd4995cb-2e6a-4485-8dbf-4b87fd144dd9@example.com...	Phone Search	Active	Edit role
e2e-screen-admin-0ac5a2c9-28d2-4250-ae79-89769f834d01...	Member	Invited	Resend

Capture SHA-256: 724bb5fc1b1b397c1a7da926d3008d538d68555ed9e9ad86355112d3052921a6

05

EXECUTED GHERKIN STEP

Then the invitation remains pending after the resend **PASS***No visible change at this step; the pending invitation projection remains visible*

The screenshot displays the MedQAIR 'Users' management page. The left sidebar contains navigation links for Home, Organisation, Bulk import, Organisation facts, Users (6), Partners (11), RELEASES, Published instructions, Release checks, Release history, History as administrator, and ACCOUNT (Sign-in and MFA). The main content area is titled 'Users' and includes a '+ Invite a user' button. Below the title, a list of users is shown with their roles, email addresses, and status. The last user, 'e2e-screen-admin', is marked as 'Invited' and has a 'Resend' button highlighted with a red circle. The interface also includes a 'Technical file' dropdown and a user profile dropdown in the top right corner.

User ID	Role	Email	Status	Action
EM	E2E Manufacturer	e2e-manufacturer@medqair.com	Organisation admin · MFA not set up · Acc...	Edit role ...
EP	E2E PRRC	e2e-prrc@medqair.com	PRRC · MFA not set up · Account updated 9 Sept 2026	Edit role ...
EE	E2E eIFU Reader	e2e-eifu-reader@medqair.com	Member · MFA not set up · Account updated ...	Edit role ...
EE	E2E eIFU Recipient	e2e-recipient@medqair.com	Member · MFA not set up · Account updated 9 ...	Edit role ...
PS	Phone Search-bd4995cb-2e6a-4485-8dbf-4b87fd144dd9	e2e-admin-phone-bd4995cb-2e6a-4485-8dbf-4b87fd144dd9@example.com...		Edit role ...
ES	e2e-screen-admin-0ac5a2c9-28d2-4250-ae79-89769f834d01...		Member · Invitation pending · Invited 9 Sept 2026 · expires 16 Sept 2...	Invited Resend ...

Capture SHA-256: 724bb5fc1b1b397c1a7da926d3008d538d68555ed9e9ad86355112d3052921a6

06

EXECUTED GHERKIN STEP

When the organisation administrator revokes that invitation **PASS**

MedQAIR Technical file

← Home

Organisation

- Bulk import
- Organisation facts
- Users** 5
- Partners 11

RELEASES

- Published instructions
- Release checks
- Release history
- History as administrator

ACCOUNT

- Sign-in and MFA

Users

Roles apply to the whole organisation. Who approves a release is set per release.

+ Invite a user

EM	E2E Manufacturer e2e-manufacturer@medqair.com · Organisation admin · MFA not set up · Acc...	Edit role	...
EP	E2E PRRC e2e-prrc@medqair.com · PRRC · MFA not set up · Account updated 9 Sept 2026	Edit role	...
EE	E2E eIFU Reader e2e-eifu-reader@medqair.com · Member · MFA not set up · Account updated ...	Edit role	...
EE	E2E eIFU Recipient e2e-recipient@medqair.com · Member · MFA not set up · Account updated 9 ...	Edit role	...
PS	Phone Search-bd4995cb-2e6a-4485-8dbf-4b87fd144dd9 e2e-admin-phone-bd4995cb-2e6a-4485-8dbf-4b87fd144dd9@example.com...	Edit role	...

Deactivating never rewrites history: the name stays on every approval and audit entry.

Capture SHA-256: e009f70697b2719922853bf2ad9285efc8c0689002d99e2e26758ee230f48f0b

07

EXECUTED GHERKIN STEP

Then the invitation is removed from the organisation user projection PASS

MedQAIR Technical file ▾

⌛ TN [TEST] Northstar Medical Im... ▾ EM

Manufacture

← Home

Organisation

- Bulk import
- Organisation facts
- Users** 5
- Partners 11

RELEASES

- Published instructions
- Release checks
- Release history
- History as administrator

ACCOUNT

- Sign-in and MFA

Users

Roles apply to the whole organisation. Who approves a release is set per release.

[+ Invite a user](#)

EM	E2E Manufacturer e2e-manufacturer@medqair.com · Organisation admin · MFA not set up · Acc...	Edit role	...
EP	E2E PRRC e2e-prrc@medqair.com · PRRC · MFA not set up · Account updated 9 Sept 2026	Edit role	...
EE	E2E eIFU Reader e2e-eifu-reader@medqair.com · Member · MFA not set up · Account updated ...	Edit role	...
EE	E2E eIFU Recipient e2e-recipient@medqair.com · Member · MFA not set up · Account updated 9 ...	Edit role	...
PS	Phone Search-bd4995cb-2e6a-4485-8dbf-4b87fd144dd9 e2e-admin-phone-bd4995cb-2e6a-4485-8dbf-4b87fd144dd9@example.com...	Edit role	...

Deactivating never rewrites history: the name stays on every approval and audit entry.

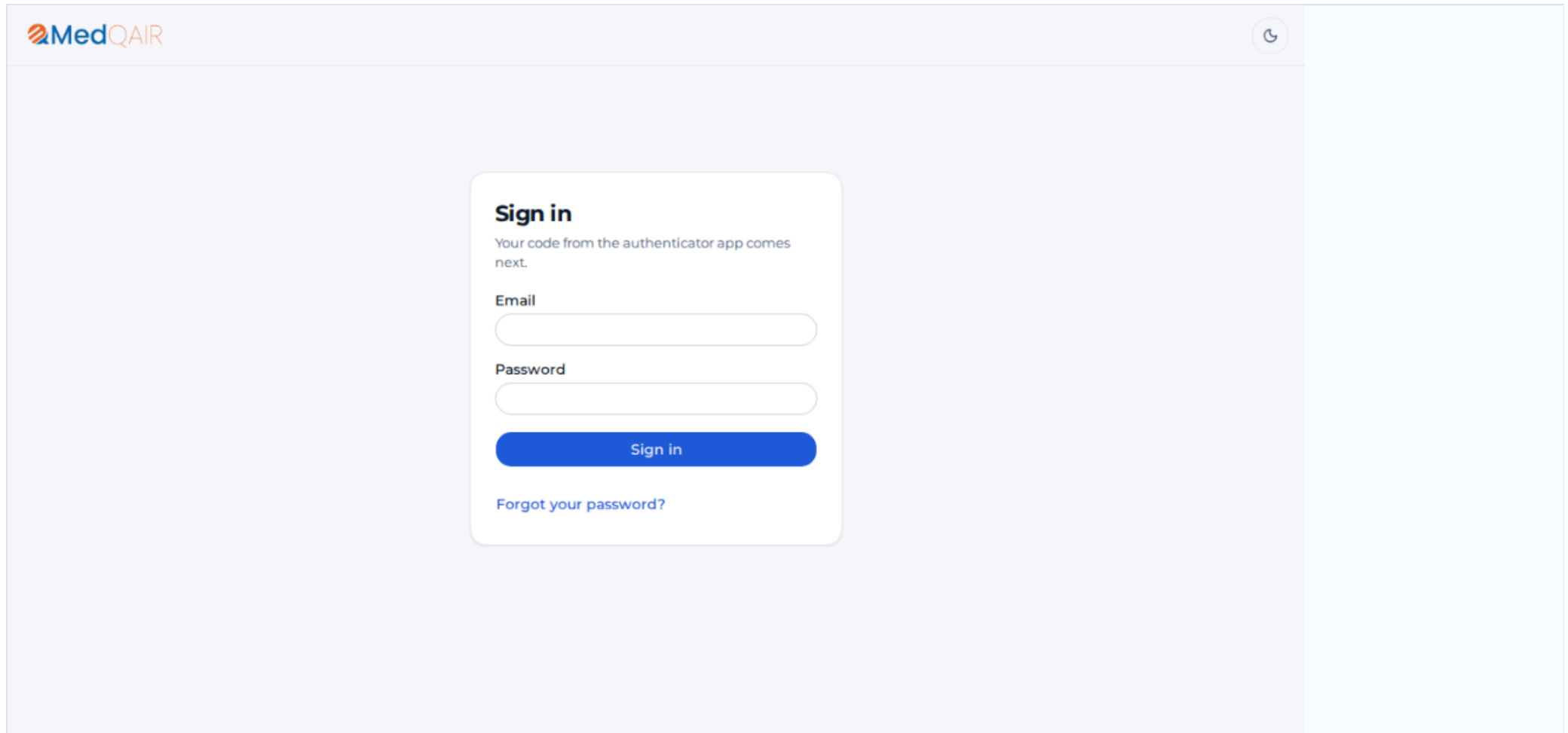
Capture SHA-256: b9bdb2eec6fe3304219d3d5c8d9b02a5a8c33b42822ff161bbe1627e336e870f

A draft document keeps its identity through details and preview

01

EXECUTED GHERKIN STEP

Given the redesign sign-in page **PASS**



Capture SHA-256: 953d9a1220a1b501a0ede3a87b7d5516c6552f0e0d727f3b59246c01ef255e3b

02

EXECUTED GHERKIN STEP

When I sign in to the redesign as a manufacturer **PASS**

 Technical file 

   [TEST] Northstar Medical Im...  

Your work

[TEST] Northstar Medical Imaging · Wednesday 9 September

 **12**
drafts to finish

 **0**
returned for changes

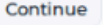
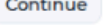
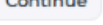
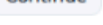
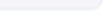
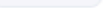
 **0**
waiting on a partner

 **41**
devices, 6 released

 Add a device

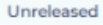
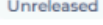
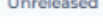
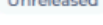
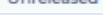
Needs you

12 drafts

	Northstar VitalSync Patient Monitor 1.1 labelling update	
	Northstar SonoLite Handheld Ultrasound 1.0 first release	
	Northstar CardioMesh Coronary Stent 1.0 first release	
	Northstar LumaDerm Phototherapy Lamp Change 1 · first release	
	E2E Journey Device 1788933641806128 Change 1 · 1.0.0 · first release	
	E2E Journey Device 1788933703671839 Change 1 · 1.0.0 · first release	

Devices · 41

 Name, UDI-DI or Basic UDI-DI

	PulseView AR Validation ...	
	AtlasView PRRC Validatio...	
	AtlasView AR Verification ...	
	AtlasView AR Validation ...	
	AtlasView Importer Verifi...	
	AtlasView Importer Rejec...	

Capture SHA-256: 2635fc1c93d52d0a66885acc0e57e65bb091a15eb467f6eff4e140170fab9ef9

03

EXECUTED GHERKIN STEP

And I open the isolated release-ledger device PASS

 Technical file 

 TN [TEST] Northstar Medical Im...  EM

Home > Devices > E2E Release Ledger Synthetic Device

 **E2E Release Ledger Synthetic Device** Released

current 1.0 released 9 Sept · Basic UDI-DI 0950600090045D

Choose who

 Start a change

Changes and releases

Release history

 **1.0**
Released 9 Sept · FIX-REL-CLEAN registered baseline

Delivered Open

Current file 1.0 · 1 document

Find

 Certificates & declarations

1 document

Declaration of Conformity · en

approved-baseline

Registration

Open

All 65 answers · ready for EUDAMED XML

Who can open it

Choose who

 **E2E Authorised Rep Co**
Nothing yet · Authorised representative

 **[TEST] Harborline Importers**
All documents

 **[TEST] Sectra Distribution**
All documents

Identification

UDI-DI
09506000900445

Capture SHA-256: 64862196cc07a402f82391bebaa2a17d15add0f622ada51f1505dd5670d4abb8

04

EXECUTED GHERKIN STEP

And I start production version "ui-v2 documents screen draft" PASS

 **Technical file** 

  **[TEST] Northstar Medical Im...**  

Home > E2E Release Ledger Synthetic Device > Change 2

 **Change 2** Draft

Version ui-v2 documents screen draft follows 1.0 released 9 Sept Rename

 **Documents** 1

 **Add files**

 **Drop PDFs here** · section guessed from the filename, you confirm

1 unchanged documents Show all

Ready to release? Ready

 **Every upload has a section.**
Settings / Review policy · Documents

 **Your representation for this market is confirmed.**
Who receives it · Release authority & reviewers

 **Waiting for one approval after release**
E2E Authorised Rep Co · approval is required before delivery

 **Registration** Checking...

Loading registration...

Open registration

Who receives it Choose who

Capture SHA-256: 33a38863baf9c53fbae1d7f1c556450d483fa67b785041d0f8e9249240313aba

05

EXECUTED GHERKIN STEP

And I add a deterministic documents-screen changed file **PASS**

 **Technical file** 

 **TN** **[TEST] Northstar Medical Im...**  **EM**

Home › E2E Release Ledger Synthetic Device › Change 2

Change 2 Draft

Version ui-v2 documents screen draft follows 1.0 released 9 Sept [Rename](#)

 **Documents** 2 · 1 changed [Add files](#)

 **Drop PDFs here** · section guessed from the filename, you confirm

 **Technical documentation** 1 document

☐ documents-screen-changed-1788933877448.pdf  ...

New

1 unchanged documents [Show all](#)

Ready to release? **Ready**

 **Every upload has a section.**
Settings / Review policy · Documents

 **Your representation for this market is confirmed.**
Who receives it · Release authority & reviewers

 **Waiting for one approval after release**
E2E Authorised Rep Co · approval is required before delivery

 **Registration** **Unchanged**

Registration matches the registered record.

[Open registration](#)

Capture SHA-256: 940cb6cc9da05105b370336b9d53395f230ceb528eb40d4c95fa0776837009bf

06

EXECUTED GHERKIN STEP

Then every current document row has the complete draft verb set **PASS**

 **Technical file** 

  **[TEST] Northstar Medical Im...**  

Home › E2E Release Ledger Synthetic Device › Change 2

 **Change 2** Draft

Version ui-v2 documents screen draft follows 1.0 released 9 Sept Rename

 **Documents** 2 · 1 changed ↑ Add files

 **Drop PDFs here** · section guessed from the filename, you confirm

 **Technical documentation** 1 document

☐ documents-screen-changed-1788933877448.pdf  

1 unchanged documents Show all

Ready to release? Ready

 **Every upload has a section.**
Settings / Review policy · Documents

 **Your representation for this market is confirmed.**
Who receives it · Release authority & reviewers

 **Waiting for one approval after release**
E2E Authorised Rep Co · approval is required before delivery

 **Registration** Unchanged

Registration matches the registered record.

Open registration

Capture SHA-256: 1a0b08d6b93fd383d61f6048da0b244d3dd88cadf5cfb455ecbcd65396e02079

07

EXECUTED GHERKIN STEP

And the documents-screen changed file preview serves its persisted PDF revision PASS

The screenshot displays the MedQAIR 'Technical file' interface. At the top, the breadcrumb path is 'Home > E2E Release Ledger Synthetic Device > Change 2'. The main header shows 'Change 2' with a 'Draft' status and a version history: 'Version ui-v2 documents screen draft follows 1.0 released 9 Sept'. Action buttons for 'Discard draft' and 'Release' are present. The 'Documents' section indicates '2 · 1 changed' and includes a 'Find' search bar and an 'Add files' button. A large dashed box prompts users to 'Drop PDFs here · section guessed from the filename, you confirm'. Below this, the 'Technical documentation' section shows '1 document' and a list containing 'documents-screen-changed-1788933877448.pdf' marked as 'New'. A 'Show all' link is provided. On the right, the 'Ready to release?' section shows a 'Ready' status and three checklist items: 'Every upload has a section.', 'Your representation for this market is confirmed.', and 'Waiting for one approval after release'. The 'Registration' section shows 'Unchanged' status and a message that 'Registration matches the registered record.', with an 'Open registration' button.

MedQAIR Technical file

Home > E2E Release Ledger Synthetic Device > Change 2

Change 2 Draft

Version ui-v2 documents screen draft follows 1.0 released 9 Sept Rename

Documents 2 · 1 changed Find Add files

Drop PDFs here · section guessed from the filename, you confirm

Technical documentation 1 document

documents-screen-changed-1788933877448.pdf New

1 unchanged documents Show all

Ready to release? Ready

- ✓ Every upload has a section.
Settings / Review policy · Documents
- ✓ Your representation for this market is confirmed.
Who receives it · Release authority & reviewers
- ✓ Waiting for one approval after release
E2E Authorised Rep Co · approval is required before delivery

Registration Unchanged

Registration matches the registered record.

Open registration

Capture SHA-256: 940cb6cc9da05105b370336b9d53395f230ceb528eb40d4c95fa0776837009bf

08

EXECUTED GHERKIN STEP

And the current document rows match their release API identities **PASS**

 **Technical file** 

 **TN** **[TEST] Northstar Medical Im...**  **EM**

Home › E2E Release Ledger Synthetic Device › Change 2

Change 2 Draft

Version ui-v2 documents screen draft follows 1.0 released 9 Sept [Rename](#)

 **Documents** 2 · 1 changed [Add files](#)

 **Drop PDFs here** · section guessed from the filename, you confirm

 **Technical documentation** 1 document

☐ documents-screen-changed-1788933877448.pdf  ...

New

1 unchanged documents [Show all](#)

Ready to release? **Ready**

 **Every upload has a section.**
Settings / Review policy · Documents

 **Your representation for this market is confirmed.**
Who receives it · Release authority & reviewers

 **Waiting for one approval after release**
E2E Authorised Rep Co · approval is required before delivery

 **Registration** **Unchanged**

Registration matches the registered record.

[Open registration](#)

Capture SHA-256: d74bb7b506fb32a00a209426738affda032092f651987ae37a5b37be8c9f05a3

09

EXECUTED GHERKIN STEP

When I discard the current documents-screen draft PASS

 Technical file ▼

 [TEST] Northstar Medical Im...
Manufacturer



Home › Devices › E2E Release Ledger Synthetic Device

 **E2E Release Ledger Synthetic Device** Released

current 1.0 released 9 Sept · Basic UDI-DI 0950600090045D

Choose who

[+ Start a change](#)

Changes and releases

Release history

 **1.0**
Released 9 Sept · FIX-REL-CLEAN registered baseline

Delivered Open

Current file 1.0 · 1 document

Find

 **Certificates & declarations**

1 document

Declaration of Conformity · en
approved-baseline

Registration

Open

All 65 answers · ready for EUDAMED XML

Who can open it

Choose who

 **E2E Authorised Rep Co**
Nothing yet · Authorised representative

 **[TEST] Harborline Importers**
All documents

 **[TEST] Sectra Distribution**
All documents

Identification

UDI-DI
09506000900445

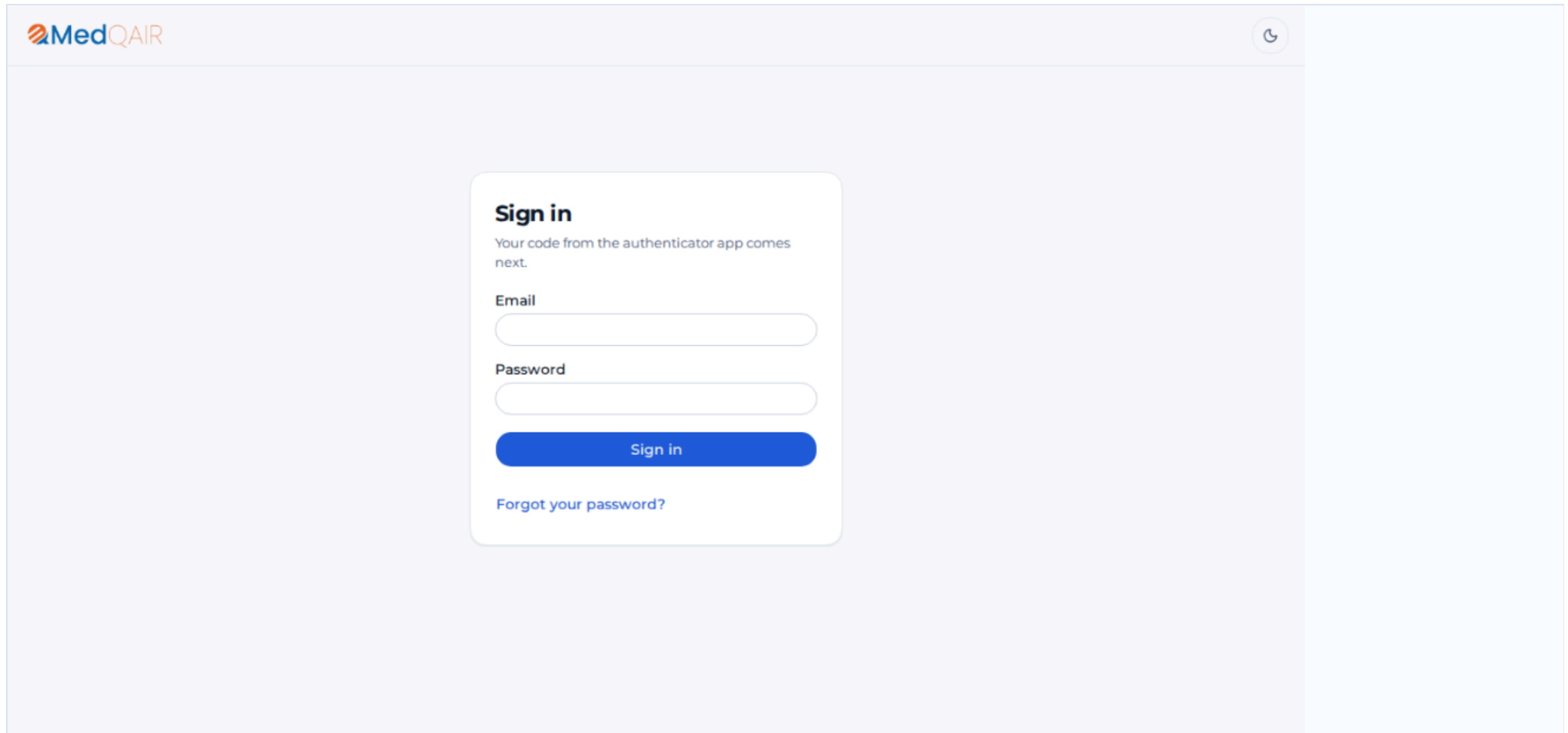
Capture SHA-256: 64862196cc07a402f82391bebaa2a17d15add0f622ada51f1505dd5670d4abb8

Expanded unchanged documents keep the same row actions after reload

01

EXECUTED GHERKIN STEP

Given the redesign sign-in page **PASS**



Capture SHA-256: 953d9a1220a1b501a0ede3a87b7d5516c6552f0e0d727f3b59246c01ef255e3b

02

EXECUTED GHERKIN STEP

When I sign in to the redesign as the EU manufacturer PASS

 Technical file 

   [TEST] Flok Health EU Manufacturer  

Your work

[TEST] Flok Health EU - Wednesday 9 September

 **15**
drafts to finish

 **0**
returned for changes

 **0**
waiting on a partner

 **19**
devices, 13 released

Needs you15 drafts

 **VitaPulse Monitor**
E2E portfolio VitaPulse Monitor registration draft · 2.0

Continue

 **Flok Posture Coach**
1.0 first release

Continue

 **E2E Journey Device 1788933721006342**
Change 2

Continue

 **E2E Journey Device 1788933770899946**
2 open drafts · Change 3

Continue

 **E2E Pagination Release History 1788933869676-240d6e19**
10 open drafts · pagination newer draft 10 cab738c9-6760-46b9-9de6-8c2f4804f41a

Continue

Devices · 19All 19 >

 **Flok Health**

Unreleased

 **Demo Registered Device**

2.0.0 released 9 SeptReleased

 **AeroVent Home**

1.0 released 9 SeptReleased

 **OrthoFix Pro**

1.0 released 9 SeptReleased

 **VitaPulse Monitor**

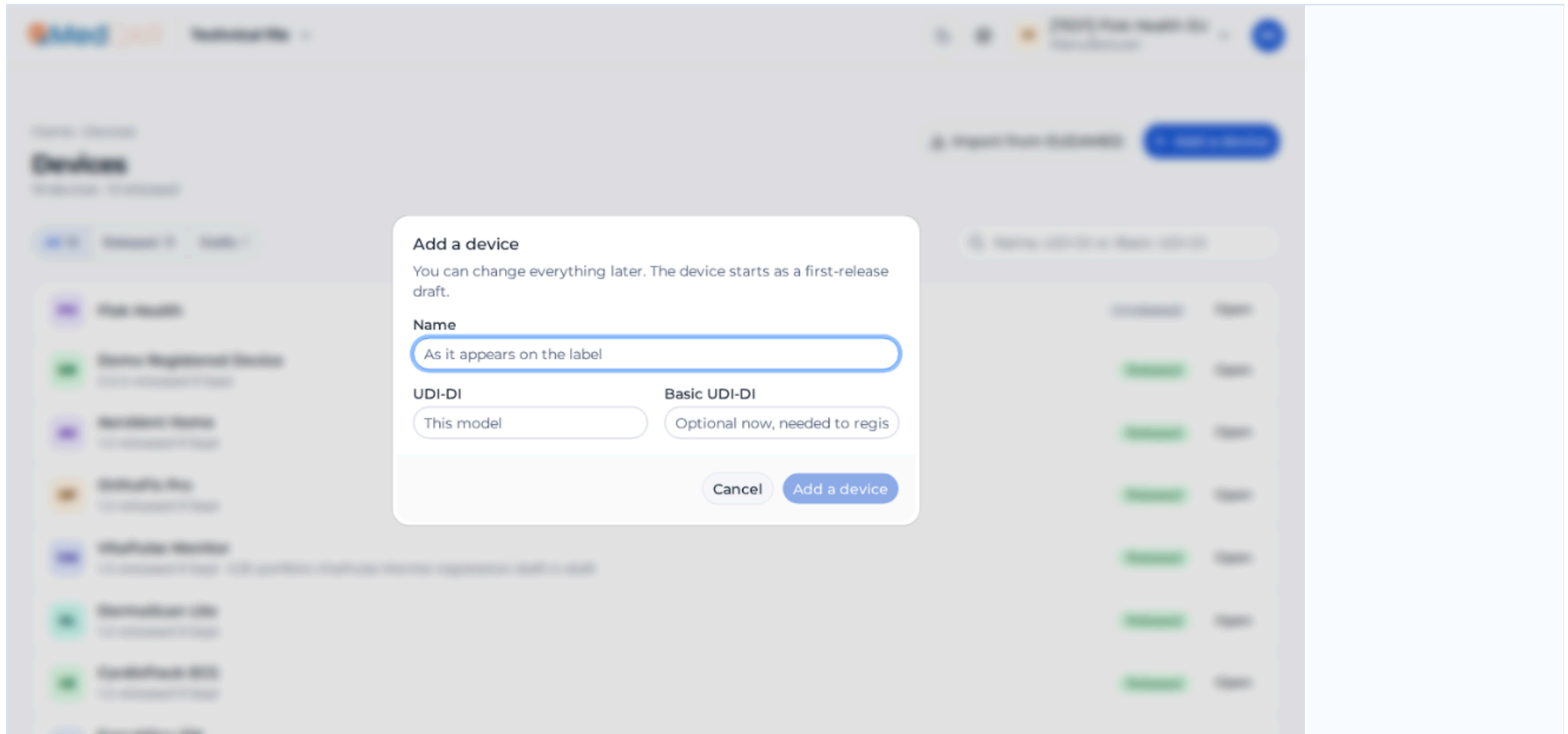
1.0 released 9 Sept · E2E portfoli...Released

 **DemoSage Lite**

Capture SHA-256: 6ff3fdd5b4ef6ce02b0e9fb47332ac609a9c6bb2748c4696187e66aad19d2351

03

EXECUTED GHERKIN STEP

And I open the redesign's add-device form PASS

Capture SHA-256: f99b58de76f2c5ebc271a0c74393f77c82f5e5274e719d288c146398133a4b58

04

EXECUTED GHERKIN STEP

And I submit a device with a unique name and UDI-DI PASS

 Technical file 

   [TEST] Flok Health EU 
Manufacturer 

Home › Devices › E2E Journey Device 1788933881637232

 **E2E Journey Device 1788933881637232** Unreleased
not released yet · Basic UDI-DI —Choose who **Changes and releases**

No changes yet.

Registration Open

Not started. EUDAMED needs every answer.

Who can open it Choose who

Only you, so far.

IdentificationUDI-DI
E2E-1788933881637232Basic UDI-DI
—UDI-PI
—

Capture SHA-256: 2a6a3c40ac21fa186f1e7ecbda17e229c76f441b778687e7c4c9580e16a4169f

05

EXECUTED GHERKIN STEP

And I start production version "ui-v2 documents screen unchanged baseline" PASS

 Technical file 

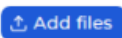
  [TEST] Flok Health EU
Manufacturer 

Home › E2E Journey Device 1788933881637232 › Change 1

 **Change 1** Draft

Version ui-v2 documents screen unchanged baseline Rename

 **Documents** 0

Find 

 **Drop PDFs here** · section guessed from the filename, you confirm

No documents yet.

Ready to release? Ready

 **Every upload has a section.**
Settings / Review policy · Documents

 **This device's target market is not recorded — add its EUDAMED registration from the device's Registration page; the registration records the market.**
Who receives it · Release authority & reviewers · recommended — you can still release
MDIS compares your organisation's country (from its SRN) with this device's market. Your representative is appointed under Who receives it — a partner you are already connected to at once, a new one once they accept the invitation. Confirming records that the appointment covers this market.
[Open Who receives it](#)

Capture SHA-256: c6a789fb3239f7632b8102140502f84a6315ddeb56c4b6bc7edc96b9ab88441c

06

EXECUTED GHERKIN STEP

And I complete the release's market facts **PASS**

 Technical file 

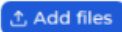
  [TEST] Flok Health EU
Manufacturer  

Home › E2E Journey Device 1788933881637232 › Change 1

 **Change 1** Draft

Version ui-v2 documents screen unchanged baseline Rename

 **Documents** 0

Find 

 **Drop PDFs here** · section guessed from the filename, you confirm

No documents yet.

Ready to release? Ready

 **Every upload has a section.**
Settings / Review policy · Documents

 **Your representation for this market is confirmed.**
Who receives it · Release authority & reviewers

 **Registration** Incomplete

33 of 65 answers · EUDAMED XML needs all 65 · not needed to release

Answer remaining 32

Open registration

Who receives it Choose who

Capture SHA-256: 0478e930b81cc6cf848d3114e10601d25035a0af2897f0c0f6e56ce83007bd49

07

EXECUTED GHERKIN STEP

And I ensure the current release has two documents PASS

 Technical file ▼

⌂ [TEST] Flok Health EU
Manufacturer EE

Home › E2E Journey Device 1788933881637232 › Change 1

Discard draft Release

Change 1 Draft

Version ui-v2 documents screen unchanged baseline Rename

Documents 2 · 2 changed Find Add files

Drop PDFs here · section guessed from the filename, you confirm

IFU & labelling 2 documents

☐ multi-eo-product-label.pdf
New 👁 ⋮

☐ eifu-multilingual.pdf
New 👁 ⋮

Ready to release? Ready

✓ Every upload has a section.
Settings / Review policy · Documents

✓ Your representation for this market is confirmed.
Who receives it · Release authority & reviewers

Registration Incomplete

33 of 65 answers · EUDAMED XML needs all 65 · not needed to release

Answer remaining 32

Open registration

Who receives it Choose who

Capture SHA-256: 75b4f2a9a8ab84a617ff6a155c0eeb55411656a2f4ed675ca6fc490eef965c08

08

EXECUTED GHERKIN STEP

And I press Release once **PASS**

 Technical file 

  [TEST] Flok Health EU
Manufacturer 

Home › E2E Journey Device 1788933881637232 › Change 1

 **Change 1** Draft
Version ui-v2 documents screen unchanged baseline Rename

 **Documents** 2 · 2 changed  Add files

 Drop PDFs here · section guessed from the filename, you confirm

 **IFU & labelling** 2 documents

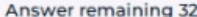
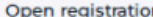
☐ multi-eo-product-label.pdf
New  ...

☐ eifu-multilingual.pdf
New  ...

Ready to release? 

 **Every upload has a section.**
Settings / Review policy · Documents

 **Your representation for this market is confirmed.**
Who receives it · Release authority & reviewers

 **Registration** 
33 of 65 answers · EUDAMED XML needs all 65 · not needed to release
 Answer remaining 32
 Open registration

Who receives it Choose who

Capture SHA-256: 1908e04db6987970fb8a8c27ffcb988fd282d0b7426e22ccb50c70171ea02992

09

EXECUTED GHERKIN STEP

Then the release is delivered immediately PASS

 Technical file 

  [TEST] Flok Health EU
Manufacturer 

Home › E2E Journey Device 1788933881637232 › Change 1

Delivered to the frozen recipient set

 **Change 1** Delivered
Version ui-v2 documents screen unchanged baseline on the market since 9 Sept

 **Documents** 2 · 2 changed · frozen as released

 **IFU & labelling** 2 documents

 multi-eo-product-label.pdf
New  ...

 eifu-multilingual.pdf
New  ...

 **Registration** Incomplete
33 of 65 answers · EUDAMED XML needs all 65 · not needed to release
Answer remaining 32
Open registration

Who receives it Choose who
Nobody receives this release.

 **Delivery**
Delivered on 2026-09-09.

Summary

Version	Documents
ui-v2 documents	2

Capture SHA-256: c77c18a2dce44e88fb5d0f91afc97ea0103be2388e5a645f6d56821e11d25c00

10

EXECUTED GHERKIN STEP

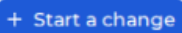
When I go back to the device PASS

 Technical file 

   [TEST] Flok Health EU
Manufacturer  

Home > Devices > E2E Journey Device 1788933881637232

 **E2E Journey Device 1788933881637232** Released
current ui-v2 documents screen unchanged baseline released 9 Sept · Basic UDI-DI E2EBASIC17889338829811

Choose who 

Changes and releases

Release history

 **ui-v2 documents screen unchanged baseline**
Released 9 Sept · Change 1 Delivered Open

Current file ui-v2 documents screen unchanged baseline · 2 documents 

 **IFU & labelling** 2 documents

multi-eo-product-label.pdf

eifu-multilingual.pdf

Registration Open

33 of 65 answers · EUDAMED XML needs all 65

Who can open it Choose who

Only you, so far.

Identification

UDI-DI
E2E-1788933881637232

Basic UDI-DI
E2EBASIC17889338829811

UDI-PI
—

Capture SHA-256: 162f1e4e69a34a00d7e78a4a727de5f2c8d9893e38bb477d52adc141f3a2cbad

11

EXECUTED GHERKIN STEP

And I start a follow-up change **PASS**

 Technical file ▼

 TF [TEST] Flok Health EU
Manufacturer ▼ EE

Home › E2E Journey Device 1788933881637232 › Change 2

 **Change 2** Draft
follows ui-v2 documents screen unchanged baseline released 9 Sept

Discard draft Release

 **Documents** 2 Find Add files

 **Drop PDFs here** · section guessed from the filename, you confirm

2 unchanged documents Show all

Ready to release? Ready

 **Every upload has a section.**
Settings / Review policy · Documents

 **Your representation for this market is confirmed.**
Who receives it · Release authority & reviewers

 **Registration** Checking...
Loading registration...
Open registration

Who receives it Choose who
Nobody receives this release.

Capture SHA-256: 07e9d7985a5e36227139acee41452b26db092915e58361127f983f64c668b5ee

12

EXECUTED GHERKIN STEP

Then expanded unchanged documents expose the complete row verb set PASS

 Technical file ▼

 TF [TEST] Flok Health EU
Manufacturer ▼ EE

Home › E2E Journey Device 1788933881637232 › Change 2

 **Change 2** Draft

follows ui-v2 documents screen unchanged baseline released 9 Sept

 Documents 2

 Add files

 Drop PDFs here · section guessed from the filename, you confirm

 IFU & labelling

2 documents

☐ multi-eo-product-label.pdf

 ...

☐ eifu-multilingual.pdf

Showing 2 unchanged documents Hide

Ready to release? Ready

 Every upload has a section.
Settings / Review policy · Documents

 Your representation for this market is confirmed.
Who receives it · Release authority & reviewers

 **Registration** Incomplete

33 of 65 answers · EUDAMED XML needs all 65 · not needed to release

Answer remaining 32

Open registration

Who receives it Choose who

Nobody receives this release

Capture SHA-256: 892eac9679e02af41e66608662f87b61efd19f87643e90e1c8029b9158fa7788

13

EXECUTED GHERKIN STEP

And the unchanged document identities remain exact after reload **PASS**

 Technical file ▼

 TF [TEST] Flok Health EU ▼ EE

Home › E2E Journey Device 1788933881637232 › Change 2

Change 2 Draft

follows ui-v2 documents screen unchanged baseline released 9 Sept

Documents 2

Find

Add files

Drop PDFs here · section guessed from the filename, you confirm

IFU & labelling

2 documents

☐ multi-eo-product-label.pdf

☐ eifu-multilingual.pdf

Showing 2 unchanged documents

Hide

Ready to release? Ready

✓ Every upload has a section.
Settings / Review policy · Documents

✓ Your representation for this market is confirmed.
Who receives it · Release authority & reviewers

Registration Incomplete

33 of 65 answers · EUDAMED XML needs all 65 · not needed to release

Answer remaining 32

Open registration

Who receives it Choose who

Nobody receives this release

Capture SHA-256: fcb6702bb8a70ec09759bb6c70bfe353ae1b17e392ef5d8fc567df495e52c022

14

EXECUTED GHERKIN STEP

And each expanded unchanged document can be deleted with release semantics PASS

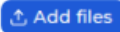
 Technical file 

  [TEST] Flok Health EU
Manufacturer  

Home › E2E Journey Device 1788933881637232 › Change 2

 **Change 2** Draft
follows ui-v2 documents screen unchanged baseline released 9 Sept

 Documents 0

Find 

 Drop PDFs here · section guessed from the filename, you confirm

 Removed in this change

2 documents

multi-eo-product-label.pdf
Removed at release — delivered copies stay — E2E unchanged removal 0-1788933888746

—

eifu-multilingual.pdf
Removed at release — delivered copies stay — E2E unchanged removal 1-1788933890055

—

Ready to release? Ready

✓ Every upload has a section.
Settings / Review policy · Documents

✓ Your representation for this market is confirmed.
Who receives it · Release authority & reviewers

 Registration Incomplete

33 of 65 answers · EUDAMED XML needs all 65 · not needed to release

Answer remaining 32

Open registration

Who receives it Choose who

Nobody receives this release

Capture SHA-256: 97cc79a6196f81d72f50a826fcef3146163c08eba497da729214d468b145e036

15

EXECUTED GHERKIN STEP

When I discard the current documents-screen draft PASS

MedQAIR

Technical file

TF

[TEST] Flok Health EU
Manufacturer

EE

Home > Devices > E2E Journey Device 1788933881637232

Choose who

+ Start a change

E2E Journey Device 1788933881637232

Released

current ui-v2 documents screen unchanged baseline released 9 Sept · Basic UDI-DI E2EBASIC17889338829811

Changes and releases

Release history

✓

ui-v2 documents screen unchanged baseline

Released 9 Sept · Change 1

Delivered

Open

Current file

ui-v2 documents screen unchanged baseline · 2 documents

Find

IFU & labelling

2 documents

multi-eo-product-label.pdf

eifu-multilingual.pdf

Registration

Open

33 of 65 answers · EUDAMED XML needs all 65

Who can open it

Choose who

Only you, so far.

Identification

UDI-DI

E2E-1788933881637232

Basic UDI-DI

E2EBASIC17889338829811

UDI-PI

—

Capture SHA-256: 46b2c0df03d801d0c519bc35fdb2f5ee6616679a73ab0d6c283fe33b5b7679d

features/release-integration/documents-screen-contract.feature · @SR-029 @MODULE:RELEASE @SECTION-CHECK @CHANGE-VIEW-ALL-DEVICES.3 @SR-030

PASS

Release checks show the owning screen for every persisted rule

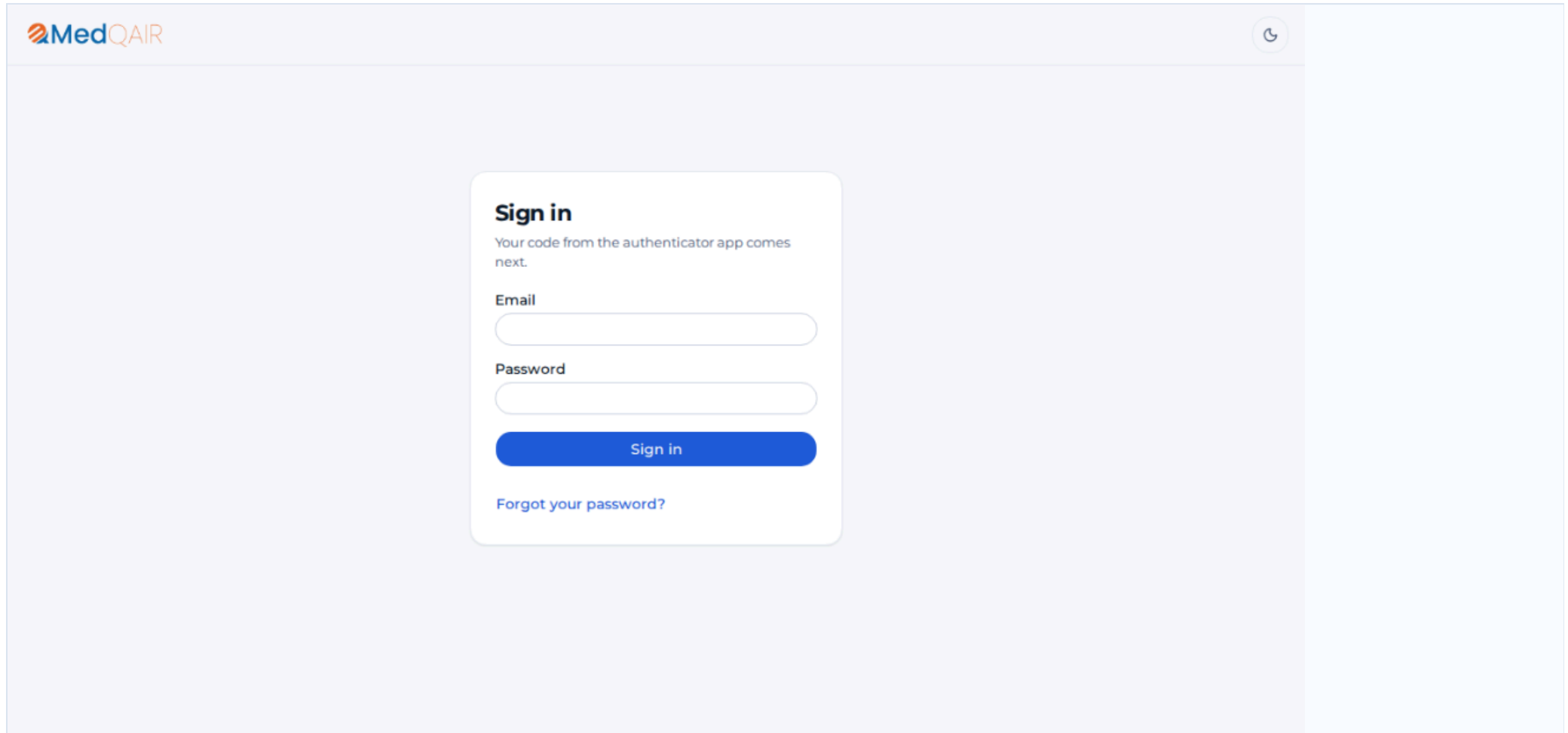
The current authority row includes its granted action and device link. This journey proves rule/state/home/owner and those controls, while the older status-only screen promise remains an

explicit requirements gap.

01

EXECUTED GHERKIN STEP

Given the redesign sign-in page **PASS**



Sign in

Your code from the authenticator app comes next.

Email

Password

Sign in

[Forgot your password?](#)

Capture SHA-256: 953d9a1220a1b501a0ede3a87b7d5516c6552f0e0d727f3b59246c01ef255e3b

02

EXECUTED GHERKIN STEP

When I sign in to the redesign as a manufacturer **PASS**

 Technical file 

   [TEST] Northstar Medical Im...  

Your work

[TEST] Northstar Medical Imaging · Wednesday 9 September

 **12**
drafts to finish

 **0**
returned for changes

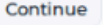
 **0**
waiting on a partner

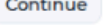
 **41**
devices, 6 released

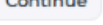
 Add a device

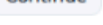
Needs you

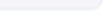
12 drafts

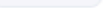
 **Northstar VitalSync Patient Monitor**
1.1 labelling update 

 **Northstar SonoLite Handheld Ultrasound**
1.0 first release 

 **Northstar CardioMesh Coronary Stent**
1.0 first release 

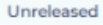
 **Northstar LumaDerm Phototherapy Lamp**
Change 1 · first release 

 **E2E Journey Device 1788933641806128**
Change 1 · 1.0.0 · first release 

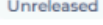
 **E2E Journey Device 1788933703671839**
Change 1 · 1.0.0 · first release 

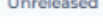
Devices · 41

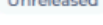
 Name, UDI-DI or Basic UDI-DI

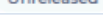
 **PulseView AR Validation ...** 

 **AtlasView PRRC Validatio...** 

 **AtlasView AR Verification ...** 

 **AtlasView AR Validation ...** 

 **AtlasView Importer Verifi...** 

 **AtlasView Importer Rejec...** 

Capture SHA-256: 2635fc1c93d52d0a66885acc0e57e65bb091a15eb467f6eff4e140170fab9ef9

03

EXECUTED GHERKIN STEP

And I set the section check to hold the release **PASS**

 Technical file 

   [TEST] Northstar Medical Im...  

Your work

[TEST] Northstar Medical Imaging · Wednesday 9 September

 **12**
drafts to finish

 **0**
returned for changes

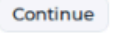
 **0**
waiting on a partner

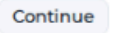
 **41**
devices, 6 released

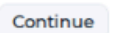
 Add a device

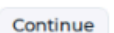
Needs you

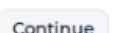
12 drafts

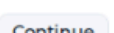
 **Northstar VitalSync Patient Monitor**
1.1 labelling update 

 **Northstar SonoLite Handheld Ultrasound**
1.0 first release 

 **Northstar CardioMesh Coronary Stent**
1.0 first release 

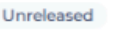
 **Northstar LumaDerm Phototherapy Lamp**
Change 1 · first release 

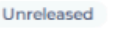
 **E2E Journey Device 1788933641806128**
Change 1 · 1.0.0 · first release 

 **E2E Journey Device 1788933703671839**
Change 1 · 1.0.0 · first release 

Devices · 41

 Name, UDI-DI or Basic UDI-DI

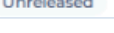
 **PulseView AR Validation ...** 

 **AtlasView PRRC Validatio...** 

 **AtlasView AR Verification ...** 

 **AtlasView AR Validation ...** 

 **AtlasView Importer Verifi...** 

 **AtlasView Importer Rejec...** 

Capture SHA-256: 9c5e9aab9af0c92826778f7b22b905c330eb4ff8a8659a677198999a7a3ce4

04

EXECUTED GHERKIN STEP

And I open the isolated release-ledger device PASS

 Technical file 

 TN [TEST] Northstar Medical Im...  EM

Home > Devices > E2E Release Ledger Synthetic Device

 **E2E Release Ledger Synthetic Device** Released

current 1.0 released 9 Sept · Basic UDI-DI 0950600090045D

Changes and releases

Release history

 **1.0**

Released 9 Sept · FIX-REL-CLEAN registered baseline

Delivered Open

Current file 1.0 · 1 document

Find

 **Certificates & declarations**

1 document

Declaration of Conformity · en

approved-baseline

Registration

Open

All 65 answers · ready for EUDAMED XML

Who can open it

Choose who

 **E2E Authorised Rep Co**

Nothing yet · Authorised representative

 **[TEST] Harborline Importers**

All documents

 **[TEST] Sectra Distribution**

All documents

Identification

UDI-DI

09506000900445

Capture SHA-256: a601312aa273974f4ce3643dba0cbf6774559139c2b6e60032815ed0e551a7ea

05

EXECUTED GHERKIN STEP

And I start production version "ui-v2 documents screen check home" PASS

MedQAIR Technical file

Home > E2E Release Ledger Synthetic Device > Change 3

Change 3 Draft

Version ui-v2 documents screen check home follows 1.0 released 9 Sept Rename

Documents 1 Find Add files

Drop PDFs here · section guessed from the filename, you confirm

1 unchanged documents Show all

Ready to release? Ready

- ✓ Every upload has a section.
Settings / Review policy · Documents
- ✓ Your representation for this market is confirmed.
Who receives it · Release authority & reviewers
- ✓ Waiting for one approval after release
E2E Authorised Rep Co · approval is required before delivery

Registration Checking...
Loading registration...
Open registration

Who receives it Choose who

Capture SHA-256: bedc4254915ba25a086452ac17cd7f45ddeaf178d313bee03e1f55fb2da8fc4b

06

EXECUTED GHERKIN STEP

And I ensure the current release has a document PASS

The screenshot displays the MedQAIR 'Technical file' interface. At the top, the MedQAIR logo is on the left, and a navigation bar includes a refresh icon, a 'TN' status, the text '[TEST] Northstar Medical Im...', and an 'EM' user icon. Below the header, the breadcrumb 'Home > E2E Release Ledger Synthetic Device > Change 3' is shown. The main section is titled 'Change 3' with a 'Draft' status. Below the title, it says 'Version ui-v2 documents screen check home follows 1.0 released 9 Sept' and has a 'Rename' link. On the right, there are 'Discard draft' and 'Release' buttons. A 'Documents' section shows '1' document, a 'Find' input, and an 'Add files' button. A dashed box contains the text 'Drop PDFs here · section guessed from the filename, you confirm'. Below this, it says '1 unchanged documents' and a 'Show all' link. On the right, a 'Ready to release?' section shows a 'Ready' status and three green checkmarks: 'Every upload has a section.' (Settings / Review policy · Documents), 'Your representation for this market is confirmed.' (Who receives it · Release authority & reviewers), and 'Waiting for one approval after release' (E2E Authorised Rep Co · approval is required before delivery). Below this is a 'Registration' section with 'Unchanged' status, stating 'Registration matches the registered record.' and an 'Open registration' button.

MedQAIR Technical file

Home > E2E Release Ledger Synthetic Device > Change 3

Change 3 Draft

Version ui-v2 documents screen check home follows 1.0 released 9 Sept Rename

Discard draft Release

Documents 1 Find Add files

Drop PDFs here · section guessed from the filename, you confirm

1 unchanged documents Show all

Ready to release? Ready

- ✓ Every upload has a section.
Settings / Review policy · Documents
- ✓ Your representation for this market is confirmed.
Who receives it · Release authority & reviewers
- ✓ Waiting for one approval after release
E2E Authorised Rep Co · approval is required before delivery

Registration Unchanged

Registration matches the registered record.

Open registration

Capture SHA-256: 0126c771fd15c7da0a52183111e08dc52525036fd15b1a50fa5352cad4935aff

07

EXECUTED GHERKIN STEP

Then every current release check names its API home and owner section **PASS***No visible change at this step; asserted through the API read*

The screenshot displays the MedQAIR 'Technical file' interface. At the top, the MedQAIR logo is on the left, and a user profile for '[TEST] Northstar Medical Im...' is on the right. The main header shows the breadcrumb 'Home > E2E Release Ledger Synthetic Device > Change 3' and two buttons: 'Discard draft' and 'Release'. Below the header, the title 'Change 3' is followed by 'Draft' and a version history: 'Version ui-v2 documents screen check home follows 1.0 released 9 Sept' with a 'Rename' link. A 'Documents' section shows '1' document, a 'Find' input, and an 'Add files' button. A dashed box prompts to 'Drop PDFs here' with a note 'section guessed from the filename, you confirm'. Below this, it states '1 unchanged documents' with a 'Show all' link. On the right, a 'Ready to release?' section shows a 'Ready' status and three checklist items: 'Every upload has a section.' (Settings / Review policy - Documents), 'Your representation for this market is confirmed.' (Who receives it - Release authority & reviewers), and 'Waiting for one approval after release' (E2E Authorised Rep Co - approval is required before delivery). At the bottom right, a 'Registration' section shows 'Unchanged' status and a note 'Registration matches the registered record.' with an 'Open registration' button.

Capture SHA-256: 0126c771fd15c7da0a52183111e08dc52525036fd15b1a50fa5352cad4935aff

08

EXECUTED GHERKIN STEP

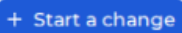
When I discard the current documents-screen draft PASS

 **Technical file** 

   **[TEST] Northstar Medical Im...**  

Home > Devices > E2E Release Ledger Synthetic Device

 **E2E Release Ledger Synthetic Device** Released
current 1.0 released 9 Sept · Basic UDI-DI 0950600090045D

Choose who 

Changes and releases

Release history

 **1.0**
Released 9 Sept · FIX-REL-CLEAN registered baseline Delivered Open

Current file 1.0 · 1 document 

 **Certificates & declarations** 1 document

Declaration of Conformity · en
approved-baseline

Registration Open

All 65 answers · ready for EUDAMED XML

Who can open it Choose who

 **E2E Authorised Rep Co**
Nothing yet · Authorised representative

 **[TEST] Harborline Importers**
All documents

 **[TEST] Sectra Distribution**
All documents

Identification

UDI-DI
09506000900445

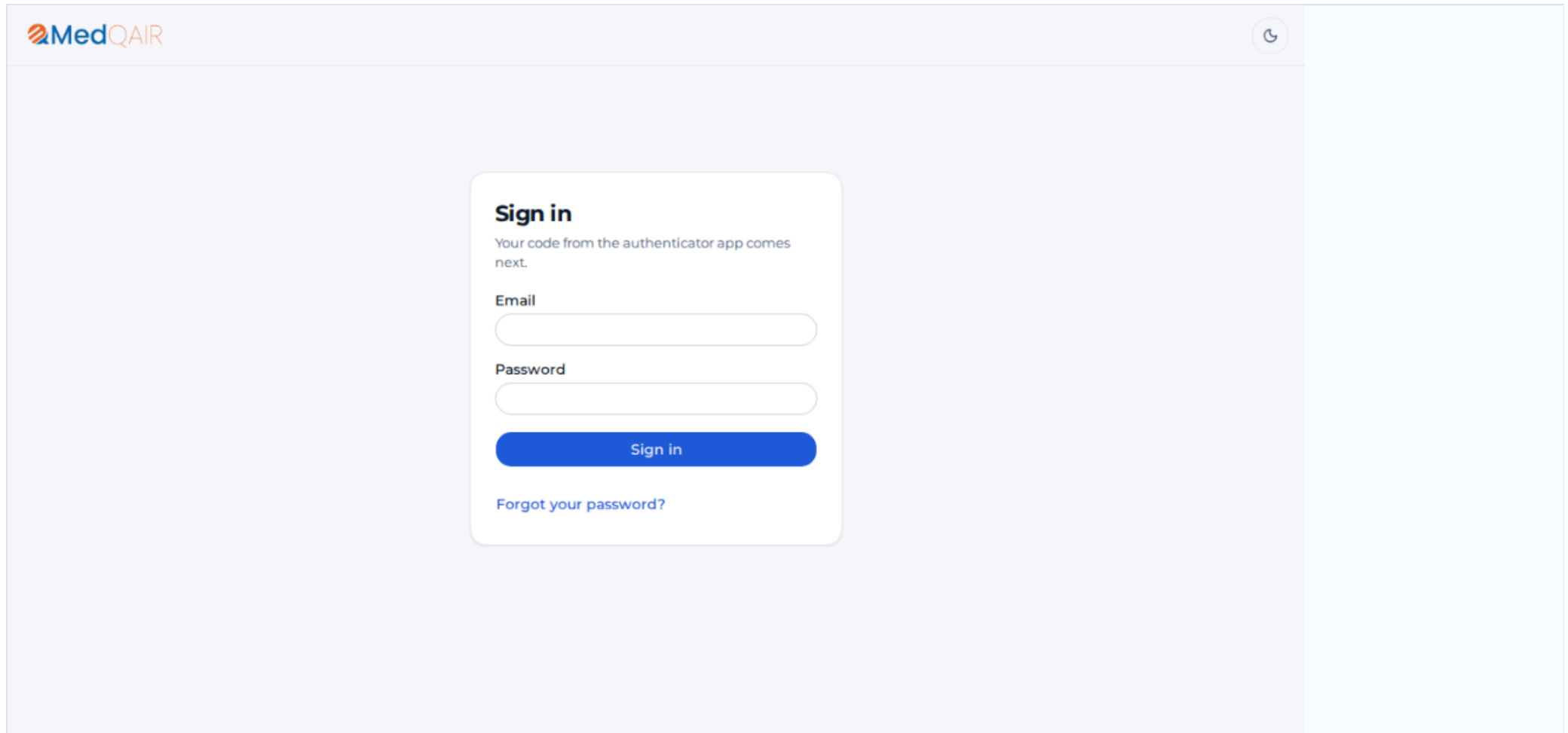
Capture SHA-256: 64862196cc07a402f82391bebaa2a17d15add0f622ada51f1505dd5670d4abb8

A changed document row names its persisted release audience

01

EXECUTED GHERKIN STEP

Given the redesign sign-in page **PASS**



Capture SHA-256: 953d9a1220a1b501a0ede3a87b7d5516c6552f0e0d727f3b59246c01ef255e3b

02

EXECUTED GHERKIN STEP

When I sign in to the redesign as a manufacturer **PASS**

 Technical file 

 **TN** [TEST] Northstar Medical Im...
Manufacturer  **EM**

Your work

[TEST] Northstar Medical Imaging · Wednesday 9 September

 **12**
drafts to finish

 **0**
returned for changes

 **0**
waiting on a partner

 **41**
devices, 6 released

 Add a device

Needs you

12 drafts

NV

Northstar VitalSync Patient Monitor
1.1 labelling update

Continue

NS

Northstar SonoLite Handheld Ultrasound
1.0 first release

Continue

NC

Northstar CardioMesh Coronary Stent
1.0 first release

Continue

NL

Northstar LumaDerm Phototherapy Lamp
Change 1 · first release

Continue



E2E Journey Device 1788933641806128
Change 1 · 1.0.0 · first release

Continue



E2E Journey Device 1788933703671839
Change 1 · 1.0.0 · first release

Continue

Devices · 41

[All 41 >](#)

PA

PulseView AR Validation ...

Unreleased

AP

AtlasView PRRC Validatio...

Unreleased

AA

AtlasView AR Verification ...

Unreleased

AA

AtlasView AR Validation ...

Unreleased

AI

AtlasView Importer Verifi...

Unreleased

AI

AtlasView Importer Rejec...

Unreleased

Capture SHA-256: 2635fc1c93d52d0a66885acc0e57e65bb091a15eb467f6eff4e140170fab9ef9

03

EXECUTED GHERKIN STEP

And I open the isolated release-ledger device PASS

 Technical file ▼

 [TEST] Northstar Medical Im...
Manufacturer ▼



Home › Devices › E2E Release Ledger Synthetic Device

 **E2E Release Ledger Synthetic Device** Released

current 1.0 released 9 Sept · Basic UDI-DI 0950600090045D

Choose who

+ Start a change

Changes and releases

Release history

 **1.0**
Released 9 Sept · FIX-REL-CLEAN registered baseline

Delivered Open

Current file 1.0 · 1 document

Find

 **Certificates & declarations**

1 document

Declaration of Conformity · en

approved-baseline

Registration

Open

All 65 answers · ready for EUDAMED XML

Who can open it

Choose who

 **E2E Authorised Rep Co**
Nothing yet · Authorised representative

 **[TEST] Harborline Importers**
All documents

 **[TEST] Sectra Distribution**
All documents

Identification

UDI-DI

09506000900445

Capture SHA-256: 64862196cc07a402f82391bebaa2a17d15add0f622ada51f1505dd5670d4abb8

04

EXECUTED GHERKIN STEP

And I start a follow-up change PASS

 Technical file 

 TN [TEST] Northstar Medical Im...  EM

Home > E2E Release Ledger Synthetic Device > Change 4

ER

Change 4 Draft

follows 1.0 released 9 Sept

 Documents 1

 Add files

 Drop PDFs here · section guessed from the filename, you confirm

1 unchanged documents [Show all](#)

Ready to release? Ready

 **Every upload has a section.**
Settings / Review policy · Documents

 **Your representation for this market is confirmed.**
Who receives it · Release authority & reviewers

 **Waiting for one approval after release**
E2E Authorised Rep Co · approval is required before delivery

 **Registration** Checking...

Loading registration...

[Open registration](#)

Who receives it Choose who

Capture SHA-256: 567bef6a52fbf3cbaf4320f11936ab8815f5eef50f6b9f529e4ddefee453fce8

05 EXECUTED GHERKIN STEP
And I add a new document to the current change and share only it with Harborline Importers PASS

MedQAIR

Technical file

TN

[TEST] Northstar Medical Im...

Manufacturer

EM

Home > E2E Release Ledger Synthetic Device > Change 4

Discard draft

Release

ER

Change 4

Draft

follows 1.0 released 9 Sept

Documents

2 · 1 changed

Find

Add files

Drop PDFs here · section guessed from the filename, you confirm

Technical documentation

1 document

☐

e2e-ledger-follow-up-label.pdf

New

[TEST] Harborline Im...

...

1 unchanged documents

Show all

Ready to release?

Ready

✓ Every upload has a section.

Settings / Review policy · Documents

✓ Your representation for this market is confirmed.

Who receives it · Release authority & reviewers

✓ Waiting for one approval after release

E2E Authorised Rep Co · approval is required before delivery

Registration

Unchanged

Registration matches the registered record.

Open registration

Capture SHA-256: a658eefc2d45f501522fb4262f0a98ccf378c309ef82d970f2679a21da8fb004

06

EXECUTED GHERKIN STEP

Then the changed document row displays its persisted sharing audience **PASS***No visible change at this step; asserted through the API read*

MedQAIR Technical file

Home > E2E Release Ledger Synthetic Device > Change 4

Change 4 Draft
follows 1.0 released 9 Sept

Documents 2 · 1 changed Find Add files

Drop PDFs here · section guessed from the filename, you confirm

Technical documentation 1 document

☐ e2e-ledger-follow-up-label.pdf [TEST] Harborline Im... ...
New

1 unchanged documents Show all

Ready to release? Ready

- ✓ Every upload has a section.
Settings / Review policy · Documents
- ✓ Your representation for this market is confirmed.
Who receives it · Release authority & reviewers
- ✓ Waiting for one approval after release
E2E Authorised Rep Co · approval is required before delivery

Registration Unchanged
Registration matches the registered record.
Open registration

Capture SHA-256: a658eefc2d45f501522fb4262f0a98ccf378c309ef82d970f2679a21da8fb004

07

EXECUTED GHERKIN STEP

When I discard the current documents-screen draft **PASS**

The screenshot shows the MedQAIR 'Technical file' interface for a device named 'E2E Release Ledger Synthetic Device'. The device is in a 'Released' state. The interface is divided into several sections:

- Header:** MedQAIR logo, 'Technical file' dropdown, navigation icons, and user information '[TEST] Northstar Medical Im...' with a role of 'Manufacturer' and a profile icon 'EM'.
- Breadcrumbs:** Home > Devices > E2E Release Ledger Synthetic Device.
- Device Card:** Displays the device name 'E2E Release Ledger Synthetic Device' with a 'Released' status, and the current version '1.0 released 9 Sept · Basic UDI-DI 0950600090045D'.
- Changes and releases:** A table showing release history. The first entry is version '1.0', released on '9 Sept', with the note 'FIX-REL-CLEAN registered baseline'. It has a 'Delivered' status and an 'Open' link.
- Current file:** Shows '1.0 · 1 document' with a 'Find' search button.
- Certificates & declarations:** A section with a document icon and the text '1 document'. Below it, a 'Declaration of Conformity · en' is listed as 'approved-baseline'.
- Registration:** A section with a progress bar and the text 'All 65 answers · ready for EUDAMED XML'. It has an 'Open' link.
- Who can open it:** A section with a 'Choose who' link. It lists three roles: 'E2E Authorised Rep Co' (Nothing yet · Authorised representative), '[TEST] Harborline Importers' (All documents), and '[TEST] Sectra Distribution' (All documents).
- Identification:** A section showing the 'UDI-DI' as '09506000900445'.

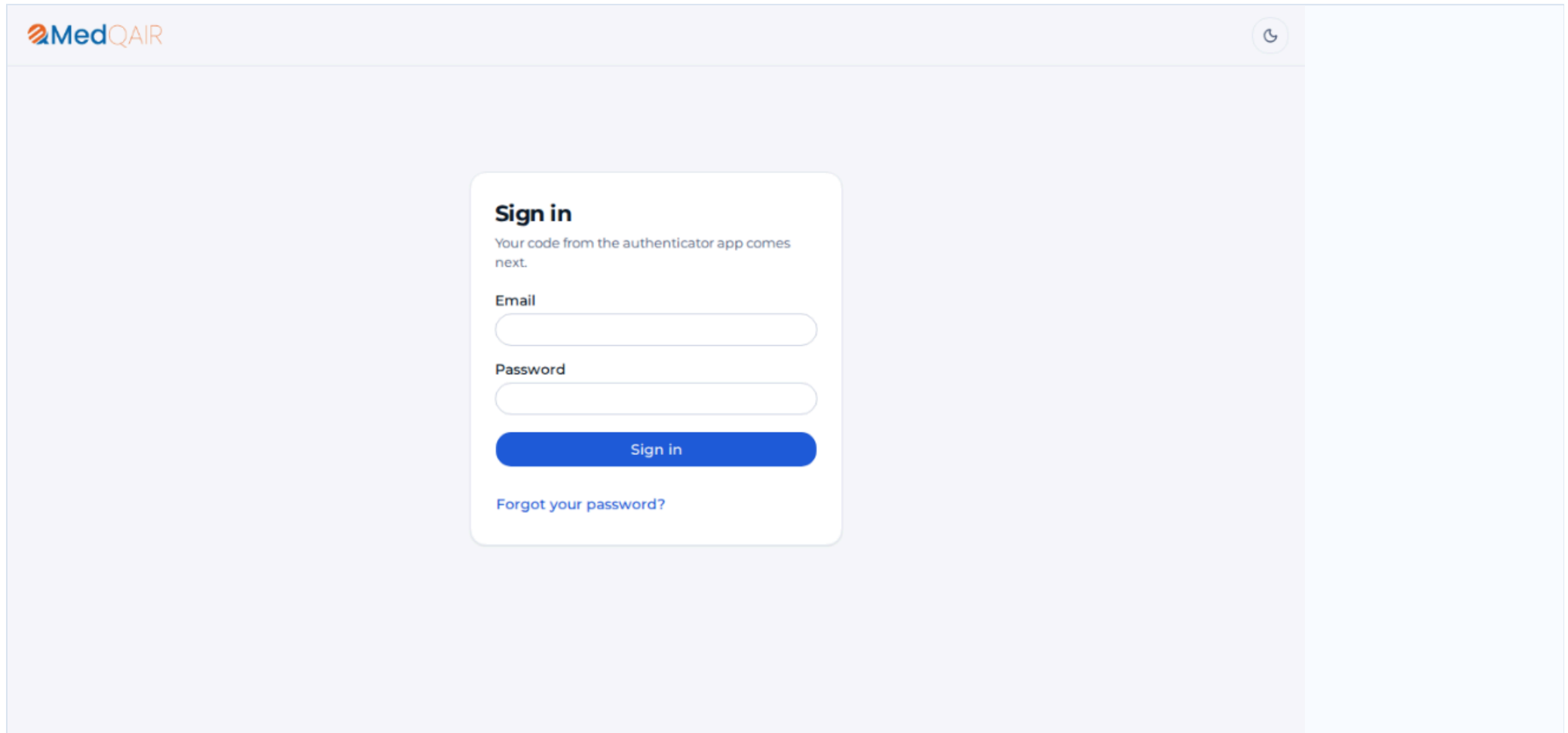
Capture SHA-256: 64862196cc07a402f82391bebaa2a17d15add0f622ada51f1505dd5670d4abb8

A document added only to a draft deletes without a release trace

01

EXECUTED GHERKIN STEP

Given the redesign sign-in page **PASS**



Capture SHA-256: 953d9a1220a1b501a0ede3a87b7d5516c6552f0e0d727f3b59246c01ef255e3b

02

EXECUTED GHERKIN STEP

When I sign in to the redesign as a manufacturer **PASS**

 Technical file 

   [TEST] Northstar Medical Im...  

Your work

[TEST] Northstar Medical Imaging · Wednesday 9 September

 **12**
drafts to finish

 **0**
returned for changes

 **0**
waiting on a partner

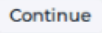
 **41**
devices, 6 released

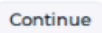
 Add a device

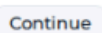
Needs you

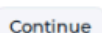
12 drafts

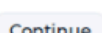
 **Northstar VitalSync Patient Monitor**
1.1 labelling update 

 **Northstar SonoLite Handheld Ultrasound**
1.0 first release 

 **Northstar CardioMesh Coronary Stent**
1.0 first release 

 **Northstar LumaDerm Phototherapy Lamp**
Change 1 · first release 

 **E2E Journey Device 1788933641806128**
Change 1 · 1.0.0 · first release 

 **E2E Journey Device 1788933703671839**
Change 1 · 1.0.0 · first release 

Devices · 41

 Name, UDI-DI or Basic UDI-DI

 **PulseView AR Validation ...** 

 **AtlasView PRRC Validatio...** 

 **AtlasView AR Verification ...** 

 **AtlasView AR Validation ...** 

 **AtlasView Importer Verifi...** 

 **AtlasView Importer Rejec...** 

Capture SHA-256: 2635fc1c93d52d0a66885acc0e57e65bb091a15eb467f6eff4e140170fab9ef9

03

EXECUTED GHERKIN STEP

And I open the isolated release-ledger device PASS

 Technical file 

 TN [TEST] Northstar Medical Im...  EM

Home > Devices > E2E Release Ledger Synthetic Device

 **E2E Release Ledger Synthetic Device** Released
current 1.0 released 9 Sept · Basic UDI-DI 0950600090045D

Choose who [+ Start a change](#)

Changes and releases

Release history

 **1.0**
Released 9 Sept · FIX-REL-CLEAN registered baseline Delivered [Open](#)

Current file 1.0 · 1 document

 [Certificates & declarations](#) 1 document

Declaration of Conformity · en
approved-baseline

Registration [Open](#)

All 65 answers · ready for EUDAMED XML

Who can open it [Choose who](#)

 **E2E Authorised Rep Co**
Nothing yet · Authorised representative

 **[TEST] Harborline Importers**
All documents

 **[TEST] Sectra Distribution**
All documents

Identification

UDI-DI
09506000900445

Capture SHA-256: 64862196cc07a402f82391bebaa2a17d15add0f622ada51f1505dd5670d4abb8

04

EXECUTED GHERKIN STEP

And I start a follow-up change PASS

 Technical file 

  [TEST] Northstar Medical Im...  

Home > E2E Release Ledger Synthetic Device > Change 5

 **Change 5** Draft
follows 1.0 released 9 Sept

Documents 1

Find

Add files

 Drop PDFs here · section guessed from the filename, you confirm

1 unchanged documents [Show all](#)

Ready to release? Ready

✓ Every upload has a section.
Settings / Review policy · Documents

✓ Your representation for this market is confirmed.
Who receives it · Release authority & reviewers

✓ Waiting for one approval after release
E2E Authorised Rep Co · approval is required before delivery

 **Registration** Unchanged

Registration matches the registered record.

Open registration

Capture SHA-256: a1cae0b3f42aa44a5ca1a502168c5e3d593ccd3114fb67f74c32bf399caa8762

05

EXECUTED GHERKIN STEP

And I add a documents-screen draft-only file PASS

 **Technical file** 

  **[TEST] Northstar Medical Im...**  

Home > E2E Release Ledger Synthetic Device > Change 5

 **Change 5** Draft
follows 1.0 released 9 Sept

 **Documents** 2 · 1 changed

 **Add files**

 **Drop PDFs here** · section guessed from the filename, you confirm

 **Technical documentation**

1 document

☐

documents-screen-draft-only-1788933904413.pdf
New

 ...

1 unchanged documents

[Show all](#)

Ready to release?

Ready

 **Every upload has a section.**
Settings / Review policy · Documents

 **Your representation for this market is confirmed.**
Who receives it · Release authority & reviewers

 **Waiting for one approval after release**
E2E Authorised Rep Co · approval is required before delivery

 **Registration**

Unchanged

Registration matches the registered record.

[Open registration](#)

Capture SHA-256: 5f31b3e05d303f29319c5d482bf3e5f3a959bf601c007a5bbc33db7f514ed849

06

EXECUTED GHERKIN STEP

Then the draft-only file has a trace-free delete confirmation **PASS**

The screenshot displays the MedQAIR 'Technical file' interface. At the top, the MedQAIR logo is on the left, and a user profile for '[TEST] Northstar Medical Im...' is on the right. The main header shows the breadcrumb 'Home > E2E Release Ledger Synthetic Device > Change 5' and two buttons: 'Discard draft' and 'Release'. Below the header, the 'Change 5' section is marked as a 'Draft' and notes it 'follows 1.0 released 9 Sept'. A 'Documents' section shows '1' document with a 'Find' input and an 'Add files' button. A dashed box indicates where to 'Drop PDFs here'. A 'Ready to release?' section shows three green checkmarks: 'Every upload has a section.', 'Your representation for this market is confirmed.', and 'Waiting for one approval after release'. A 'Registration' section shows 'Unchanged' status and an 'Open registration' button.

MedQAIR Technical file

Home > E2E Release Ledger Synthetic Device > Change 5

Change 5 Draft
follows 1.0 released 9 Sept

Discard draft Release

Documents 1 Find Add files

Drop PDFs here - section guessed from the filename, you confirm

1 unchanged documents Show all

Ready to release? Ready

- ✓ Every upload has a section.
Settings / Review policy · Documents
- ✓ Your representation for this market is confirmed.
Who receives it · Release authority & reviewers
- ✓ Waiting for one approval after release
E2E Authorised Rep Co · approval is required before delivery

Registration Unchanged
Registration matches the registered record.
Open registration

Capture SHA-256: a1cae0b3f42aa44a5ca1a502168c5e3d593ccd3114fb67f74c32bf399caa8762

07

EXECUTED GHERKIN STEP

And the draft-only file is absent from the current API after deletion PASS*No visible change at this step; asserted through the API read*

The screenshot displays the MedQAIR interface for a 'Technical file'. The top navigation bar includes the MedQAIR logo, a dropdown menu for 'Technical file', and user information for '[TEST] Northstar Medical Im...' with a 'TN' badge and 'EM' role. The main content area shows a breadcrumb trail: 'Home > E2E Release Ledger Synthetic Device > Change 5'. The 'Change 5' section is marked as a 'Draft' and notes it 'follows 1.0 released 9 Sept'. On the right, there are 'Discard draft' and 'Release' buttons. Below this, a 'Documents' section shows '1' document with a 'Find' input and an 'Add files' button. A dashed box indicates where to 'Drop PDFs here' with a note: 'section guessed from the filename, you confirm'. It also states '1 unchanged documents' with a 'Show all' link. To the right, a 'Ready to release?' section shows a 'Ready' status and three green checkmarks: 'Every upload has a section.' (Settings / Review policy · Documents), 'Your representation for this market is confirmed.' (Who receives it · Release authority & reviewers), and 'Waiting for one approval after release' (E2E Authorised Rep Co · approval is required before delivery). Below this, a 'Registration' section shows 'Unchanged' status and a message: 'Registration matches the registered record.' with an 'Open registration' button.

Capture SHA-256: a1cae0b3f42aa44a5ca1a502168c5e3d593ccd3114fb67f74c32bf399caa8762

08

EXECUTED GHERKIN STEP

When I discard the current documents-screen draft PASS

The screenshot shows the MedQAIR 'Technical file' interface for a device named 'E2E Release Ledger Synthetic Device'. The device is marked as 'Released' and has a 'current 1.0' version released on 9 Sept with a Basic UDI-DI of 0950600090045D. The interface is divided into several sections:

- Changes and releases:** Shows a table with one entry for version 1.0, released on 9 Sept, with a 'FIX-REL-CLEAN' registered baseline. The status is 'Delivered' and 'Open'.
- Current file:** Shows '1.0 - 1 document' with a 'Find' button.
- Certificates & declarations:** Shows '1 document'.
- Declaration of Conformity:** Shows 'en approved-baseline'.
- Registration:** Shows 'All 65 answers - ready for EUDAMED XML'.
- Who can open it:** Lists three roles: 'E2E Authorised Rep Co' (Nothing yet - Authorised representative), '[TEST] Harborline Importers' (All documents), and '[TEST] Sectra Distribution' (All documents).
- Identification:** Shows the UDI-DI '09506000900445'.

At the top right, there are navigation icons and a dropdown menu for '[TEST] Northstar Medical Im...' with a 'Manufacturer' label. A 'Choose who' button and a '+ Start a change' button are also visible.

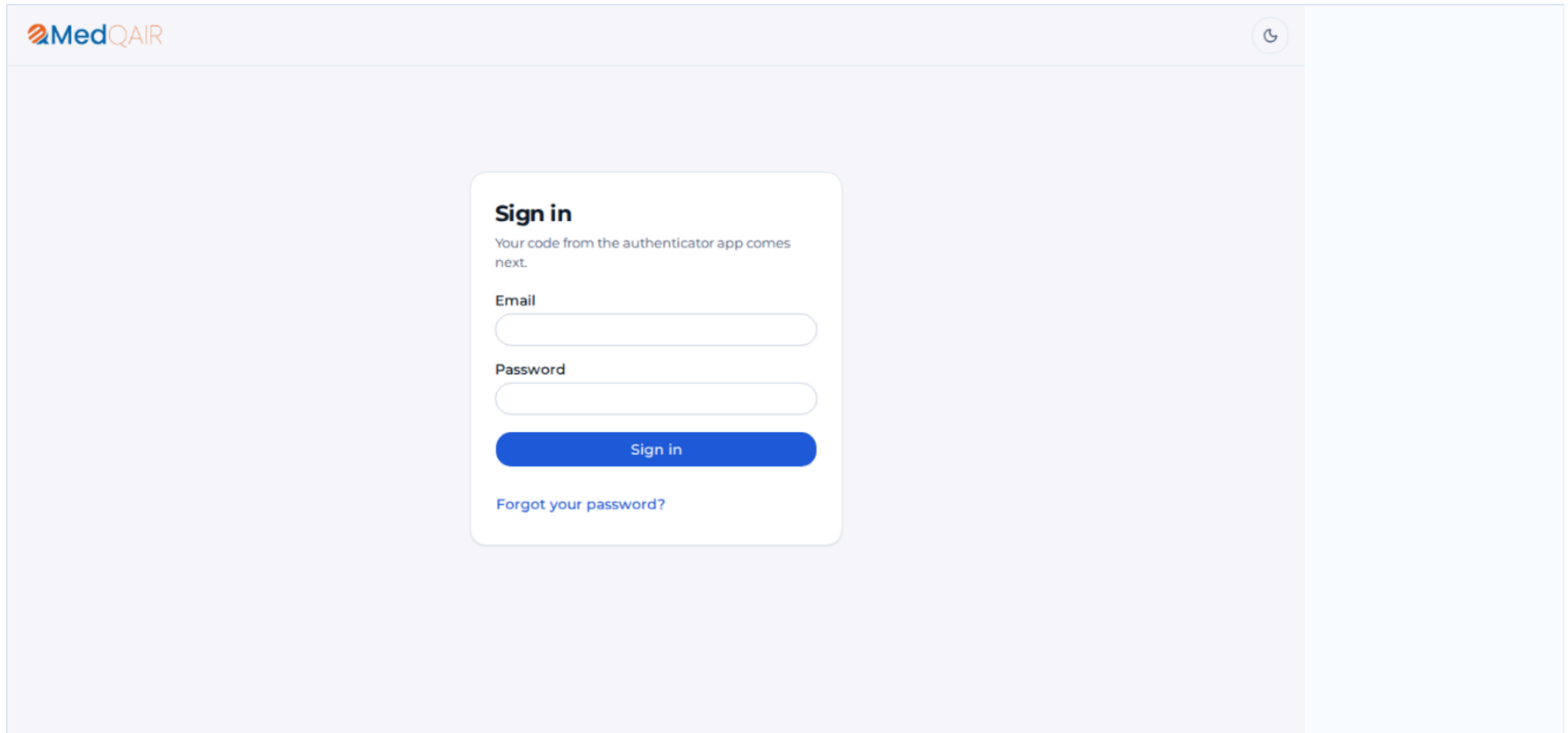
Capture SHA-256: 64862196cc07a402f82391bebaa2a17d15add0f622ada51f1505dd5670d4abb8

The current MDR editor exposes six sections and authority choices

01

EXECUTED GHERKIN STEP

Given the redesign sign-in page **PASS**



Capture SHA-256: 953d9a1220a1b501a0ede3a87b7d5516c6552f0e0d727f3b59246c01ef255e3b

02

EXECUTED GHERKIN STEP

When I sign in to the redesign as the EU manufacturer PASS

 Technical file 

   [TEST] Flok Health EU
Manufacturer  

Your work

[TEST] Flok Health EU - Wednesday 9 September

 **5**
drafts to finish

 **0**
returned for changes

 **0**
waiting on a partner

 **16**
devices, 12 released

Needs you

5 drafts

 **VitaPulse Monitor**
E2E portfolio VitaPulse Monitor registration draft · 2.0

Continue

 **Flok Posture Coach**
1.0 first release

Continue

 **E2E Journey Device 1788933721006342**
Change 2

Continue

 **E2E Journey Device 1788933770899946**
2 open drafts · Change 3

Continue

Devices · 16

All 16 >

 **Flok Health**

Unreleased

 **Demo Registered Device**
2.0.0 released 9 Sept

Released

 **SecurView DX**
1.0 released 9 Sept

Released

 **AeroVent Home**
1.0 released 9 Sept

Released

 **OrthoFix Pro**
1.0 released 9 Sept

Released

 **VitaPulse Monitor**

Capture SHA-256: 241514f5cc424e915d839e844265f7671c8cb008bc34a006641154eb02e70483

MDIS walkthrough · 251 / 418

03

EXECUTED GHERKIN STEP

And I open the seeded registered device **PASS**

 Technical file 

 TF [TEST] Flok Health EU  EE
Manufacturer

Home › Devices › Demo Registered Device

DR

Demo Registered Device Released

current 2.0.0 released 9 Sept · Basic UDI-DI 099999999910W2

Choose who

+ Start a change

Changes and releases

Release history

✓ 2.0.0 Released 9 Sept · Change 3	Delivered	Open
✓ 2.0.0 Released 9 Sept · Change 2	Delivered	Open
✓ Demo registered baseline Released 9 Sept	Delivered	Open

Current file 2.0.0 · 3 documents

Find

 Technical documentation	2 documents
happy-path-annex-vi-dataset.pdf	
happy-path-annex-vi-dataset.pdf	
 Certificates & declarations	1 document

Registration

Open

All 65 answers · ready for EUDAMED XML

Who can open it

Choose who

Only you, so far.

Identification

UDI-DI
099999999990007

Basic UDI-DI
099999999910W2

UDI-PI
—

Capture SHA-256: d42188f4b4be129aeb96984d47846f3350a35b64ec41c5f7b038f29b0278ffa7

04

EXECUTED GHERKIN STEP

And I start a documents-only registration screen change PASS

MedQAIR Technical file TF [TEST] Flok Health EU Manufacturer EE

Home > Demo Registered Device > Change 6

Change 6 Draft
follows 2.0.0 released 9 Sept

Discard draft Release

Documents 3 Find Add files

Drop PDFs here - section guessed from the filename, you confirm

3 unchanged documents Show all

Ready to release? Ready

- ✓ Every upload has a section.
Settings / Review policy · Documents
- ✓ Your representation for this market is confirmed.
Who receives it · Release authority & reviewers

Registration Checking...
Loading registration...
Open registration

Who receives it Choose who
Nobody receives this release.

Capture SHA-256: 422fd8104018147055a580ea6a776d2010a85af351b169d1f6224c59e9e39185

05

EXECUTED GHERKIN STEP

And I follow the screen change's persistent registration link PASS

 Technical file 

   [TEST] Flok Health EU
Manufacturer  

Home > Demo Registered Device > Registration

 **Registration** Unchanged

Demo Registered Device · EUDAMED device registration · 65 of 65 answered · edits ride Change 6

Not checked

Check registration

EUDAMED, by hand

1 · Produce the package.
Check the current answers. Releasing the whole change records them before its EUDAMED XML can be generated.
Use the action bar below to validate and complete these answers. After release, the same action prepares the XML download.

2 · A person uploads it to EUDAMED.
A person uploads the generated XML to EUDAMED; MDIS does not submit it.

3 · Compare with EUDAMED on demand.
Compare the stored device version with EUDAMED on demand.

Check EUDAMED now

1. Device identification
13 / 13

2. Markets & countries
4 / 4

3. Clinical / intended

Device identification 13 questions

Which EU regulation covers this device?  Help

EUDAMED: applicable regulation

MDR (EU) 2017/745

Progress

65 of 65 · XML needs all 65

In this change

Nothing edited yet. Registered answers stay as they are.

Help

Each question shows EUDAMED's own guidance from its help button. The XML is produced here and uploaded to EUDAMED by hand; MDIS submits nothing itself.

Capture SHA-256: 7d9f557c92c7be7ba1425c508576a672a9ef4e77ea7e34eb5d98d02fe5bf1af5

06

EXECUTED GHERKIN STEP

Then the current MDR registration sections and authority choices are visible PASS

 Technical file 

   [TEST] Flok Health EU
Manufacturer  

A person uploads the generated XML to EUDAMED; MDIS does not submit it.

3 · Compare with EUDAMED on demand.
Compare the stored device version with EUDAMED on demand.

[Check EUDAMED now](#)

1. Device identification
13 / 13

2. Markets & countries
4 / 4

3. Clinical / intended purpose
16 / 16

4. Risk class & rules
3 / 3

5. Sterilisation & safety
15 / 15

6. Certificates & UDI
14 / 14

Certificates & UDI14 questions

What type of certificate covers this device?
EUDAMED: certificate type · MDR Art. 56

 [Help](#) Not required for this device's regulation and risk class.

What is the certificate number and notified body?
EUDAMED: certificate number · notified body

 [Help](#) Not required for this device's regulation and risk class.

Is a UDI marked permanently on the device itself?
EUDAMED: direct marking DI · Annex VI C 4

 [Help](#)

Yes — separate direct-marking DI

Yes — same as the UDI-DI

No

Issuing Entity
EUDAMED: direct marking issuing entity

 [Help](#) Not asked — the controlling answer does not apply.

Direct Marking DI
EUDAMED: direct marking UDI-DI

 [Help](#) Not asked — the controlling answer does not apply.

Help

Each question shows EUDAMED's own guidance from its help button. The XML is produced here and uploaded to EUDAMED by hand; MDIS submits nothing itself.

Capture SHA-256: 48c3d6b5e295f97a1a2489686d21c1ef9b89d32137031a66a65c5ec4770e5cb4

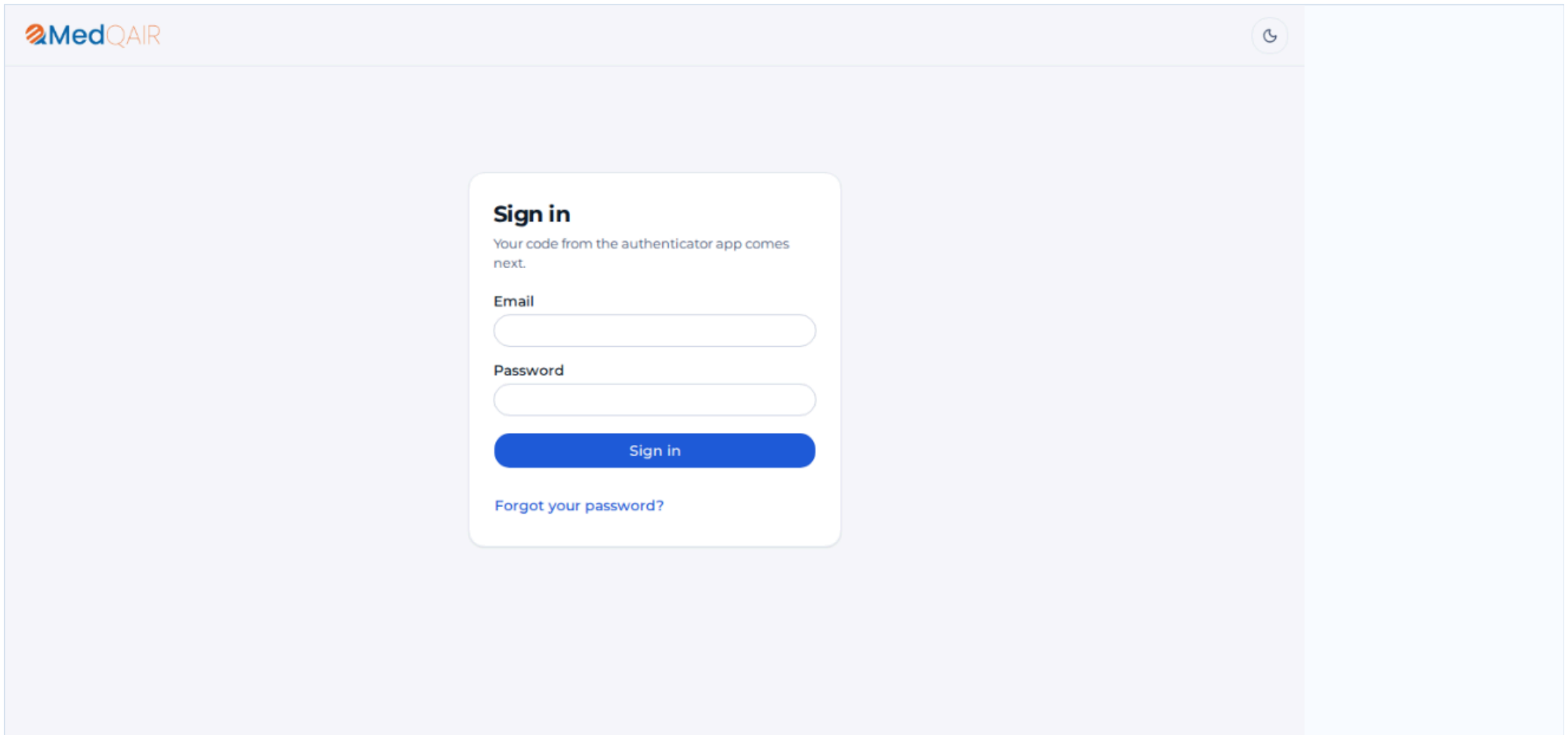
MDIS walkthrough · 255 / 418

A saved text answer rides its change and reverting removes the answer diff

01

EXECUTED GHERKIN STEP

Given the redesign sign-in page **PASS**



Capture SHA-256: 953d9a1220a1b501a0ede3a87b7d5516c6552f0e0d727f3b59246c01ef255e3b

02

EXECUTED GHERKIN STEP

When I sign in to the redesign as the EU manufacturer PASS

 Technical file 

   [TEST] Flok Health EU
Manufacturer  

Your work

[TEST] Flok Health EU - Wednesday 9 September

 **5**
drafts to finish

 **0**
returned for changes

 **0**
waiting on a partner

 **16**
devices, 12 released

Needs you5 drafts

 **VitaPulse Monitor**
E2E portfolio VitaPulse Monitor registration draft · 2.0

Continue

 **Flok Posture Coach**
1.0 first release

Continue

 **E2E Journey Device 1788933721006342**
Change 2

Continue

 **E2E Journey Device 1788933770899946**
2 open drafts · Change 3

Continue

Devices · 16All 16 >

 **Flok Health**Unreleased

 **Demo Registered Device**
2.0.0 released 9 SeptReleased

 **SecurView DX**
1.0 released 9 SeptReleased

 **AeroVent Home**
1.0 released 9 SeptReleased

 **OrthoFix Pro**
1.0 released 9 SeptReleased

 **VitaPulse Monitor**

Capture SHA-256: 241514f5cc424e915d839e844265f7671c8cb008bc34a006641154eb02e70483

03

EXECUTED GHERKIN STEP

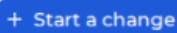
And I open the seeded registered device PASS

 Technical file 

   [TEST] Flok Health EU  
Manufacturer

Home › Devices › Demo Registered Device

 **Demo Registered Device** Released
current 2.0.0 released 9 Sept · Basic UDI-DI 099999999910W2

Choose who 

Changes and releases

Release history

 **2.0.0**
Released 9 Sept · Change 3

 **2.0.0**
Released 9 Sept · Change 2

 **Demo registered baseline**
Released 9 Sept

Delivered

Open

Delivered

Open

Delivered

Open

Current file 2.0.0 · 3 documents

Find

 **Technical documentation** 2 documents

happy-path-annex-vi-dataset.pdf

happy-path-annex-vi-dataset.pdf

 **Certificates & declarations** 1 document

Registration 

All 65 answers · ready for EUDAMED XML

Who can open it 

Only you, so far.

Identification

UDI-DI
099999999990007

Basic UDI-DI
099999999910W2

UDI-PI
—

Capture SHA-256: d42188f4b4be129aeb96984d47846f3350a35b64ec41c5f7b038f29b0278ffa7

04

EXECUTED GHERKIN STEP

And I start a documents-only registration screen change PASS

The screenshot displays the MedQAIR 'Technical file' interface. At the top, the MedQAIR logo is on the left, and the user profile '[TEST] Flok Health EU Manufacturer' is on the right. The main header shows the breadcrumb 'Home > Demo Registered Device > Change 7' and two buttons: 'Discard draft' and 'Release'. Below the header, the title 'Change 7' is marked as a 'Draft' and notes it 'follows 2.0.0 released 9 Sept'. A 'Documents' section shows '3' documents, a 'Find' search bar, and an 'Add files' button. A dashed box indicates where to 'Drop PDFs here'. Below this, it states '3 unchanged documents' with a 'Show all' link. On the right, a 'Ready to release?' section shows a 'Ready' status and two checked items: 'Every upload has a section.' and 'Your representation for this market is confirmed.' Below this is a 'Registration' section with a 'Checking...' status and an 'Open registration' button. The bottom section is 'Who receives it', with a 'Choose who' button and the text 'Nobody receives this release.'

MedQAIR Technical file

[TEST] Flok Health EU Manufacturer

Home > Demo Registered Device > Change 7

Change 7 Draft
follows 2.0.0 released 9 Sept

Discard draft Release

Documents 3 Find Add files

Drop PDFs here - section guessed from the filename, you confirm

3 unchanged documents Show all

Ready to release? Ready

- ✓ Every upload has a section.
Settings / Review policy · Documents
- ✓ Your representation for this market is confirmed.
Who receives it · Release authority & reviewers

Registration Checking...
Loading registration...
Open registration

Who receives it Choose who
Nobody receives this release.

Capture SHA-256: b1071cd382258b9b0bc34fc02390c8cbeec6b865a1eb2f2e1d7f975fd46d1613

05

EXECUTED GHERKIN STEP

And I follow the screen change's persistent registration link PASS

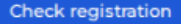
 Technical file 

   [TEST] Flok Health EU
Manufacturer  

Home > Demo Registered Device > Registration

 **Registration** Unchanged

Demo Registered Device · EUDAMED device registration · 65 of 65 answered · edits ride Change 7

Not checked  

EUDAMED, by hand

1 · Produce the package.
Check the current answers. Releasing the whole change records them before its EUDAMED XML can be generated.
Use the action bar below to validate and complete these answers. After release, the same action prepares the XML download.

2 · A person uploads it to EUDAMED.
A person uploads the generated XML to EUDAMED; MDIS does not submit it.

3 · Compare with EUDAMED on demand.
Compare the stored device version with EUDAMED on demand.




65 of 65 · XML needs all 65

In this change

Nothing edited yet. Registered answers stay as they are.

Help

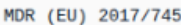
Each question shows EUDAMED's own guidance from its help button. The XML is produced here and uploaded to EUDAMED by hand; MDIS submits nothing itself.

 13 / 13

 4 / 4



Device identification 13 questions

Which EU regulation covers this device?  

EUDAMED: applicable regulation

Capture SHA-256: 283ae004ad603dd6e812c8d8441ac798f38a5a866b93405e2c3ff472c9122c43

06

EXECUTED GHERKIN STEP

And I save a different registration device version PASS

 **Technical file** 

   **[TEST] Flok Health EU** 
Manufacturer 

Check the current answers. Releasing the whole change records them before its EUDAMED XML can be generated. Use the action bar below to validate and complete these answers. After release, the same action prepares the XML download.

2 · A person uploads it to EUDAMED.
A person uploads the generated XML to EUDAMED; MDIS does not submit it.

3 · Compare with EUDAMED on demand.
Compare the stored device version with EUDAMED on demand.

[Check EUDAMED now](#)

1. Device identification
13 / 13 · 1 answer changed

2. Markets & countries
4 / 4

3. Clinical / intended purpose
16 / 16

4. Risk class & rules
3 / 3

5. Sterilisation & safety
15 / 15

6. Certificates & UDI
14 / 14

Device identification 13 questions

Which EU regulation covers this device?  [Help](#)

MDR (EU) 2017/745

EUDAMED: applicable regulation

Trade name  [Help](#)

Not asked — the controlling answer does not apply.

EUDAMED: device trade name · Annex VI A 2.1

Basic UDI-DI  [Help](#)

099999999910W2

EUDAMED: Basic UDI-DI · Annex VI B 1

UDI-DI  [Help](#)

09999999990007

EUDAMED: UDI-DI · Annex VI B 2

Device Version  [Help](#)

Screen-registration-1788933808839

EUDAMED: device version

Device version
E2E-1788933787609 → Screen-registration-1788933808839

Released with Change 7. Registered answers stay until then.

Help
Each question shows EUDAMED's own guidance from its help button. The XML is produced here and uploaded to EUDAMED by hand; MDIS submits nothing itself.

Capture SHA-256: 63d7e64d0063c0beacf777a124709579a4b601f0df5fbc7d5f51e32763523f8a

07

EXECUTED GHERKIN STEP

Then the saved text answer and carrying change name agree **PASS**

 **Technical file** 

   **[TEST] Flok Health EU** 
Manufacturer 

Check the current answers. Releasing the whole change records them before its EUDAMED XML can be generated. Use the action bar below to validate and complete these answers. After release, the same action prepares the XML download.

2 · A person uploads it to EUDAMED.
A person uploads the generated XML to EUDAMED; MDIS does not submit it.

3 · Compare with EUDAMED on demand.
Compare the stored device version with EUDAMED on demand.

[Check EUDAMED now](#)

1. Device identification
13 / 13 · 1 answer changed

2. Markets & countries
4 / 4

3. Clinical / intended purpose
16 / 16

4. Risk class & rules
3 / 3

5. Sterilisation & safety
15 / 15

6. Certificates & UDI
14 / 14

Device identification 13 questions

Which EU regulation covers this device?  [Help](#) **MDR (EU) 2017/745**
EUDAMED: applicable regulation

Trade name  [Help](#) *Not asked — the controlling answer does not apply.*
EUDAMED: device trade name · Annex VI A 2.1

Basic UDI-DI  [Help](#) **099999999910W2**
EUDAMED: Basic UDI-DI · Annex VI B 1

UDI-DI  [Help](#) **09999999990007**
EUDAMED: UDI-DI · Annex VI B 2

Device Version  [Help](#) **Screen-registration-1788933808839**
EUDAMED: device version

Device version
E2E-1788933787609 → Screen-registration-1788933808839

Released with Change 7. Registered answers stay until then.

Help

Each question shows EUDAMED's own guidance from its help button. The XML is produced here and uploaded to EUDAMED by hand; MDIS submits nothing itself.

Capture SHA-256: a71124779374b6a608169d4bcf0ebf7ca8fada8e7434505639dc427594099570

08

EXECUTED GHERKIN STEP

When I follow the editor back to its change PASS

 Technical file ▼

 TF [TEST] Flok Health EU ▼ EE

Manufacturer

Home › Demo Registered Device › Change 7

DR **Change 7** Draft
follows 2.0.0 released 9 Sept

Discard draft Release

 **Documents** 3

 Add files

 **Drop PDFs here** · section guessed from the filename, you confirm

3 unchanged documents Show all

Ready to release? Ready

 **Every upload has a section.**
Settings / Review policy · Documents

 **Your representation for this market is confirmed.**
Who receives it · Release authority & reviewers

 **Registration** Changed

1 answer differs from the registered record.

> Show 1 registration change

Open registration

Who receives it Choose who

Nobody receives this release.

Capture SHA-256: 06669f7bfd1be6175490ae60153ce78297bf6427fd582ca7241f1b408f94a577

09

EXECUTED GHERKIN STEP

Then the change card shows the saved text answer diff PASS

 Technical file ▼

🔄 TF [TEST] Flok Health EU ▼ EE
Manufacturer

Home › Demo Registered Device › Change 7

DR **Change 7** Draft
follows 2.0.0 released 9 Sept

Discard draft Release

📄 Documents 3 Find 📁 Add files

📁 Drop PDFs here · section guessed from the filename, you confirm

3 unchanged documents Show all

Ready to release? Ready

✓ **Every upload has a section.**
Settings / Review policy · Documents

✓ **Your representation for this market is confirmed.**
Who receives it · Release authority & reviewers

🌐 **Registration** Changed
1 answer differs from the registered record.

▼ Show 1 registration change

Device
Version
E2E-
1788033787600
→
Screen-
registration-

Capture SHA-256: 3526e10e70cbd71e3df446d98d862ec52a32859dfdc4cb4bbe920ba5b2bf6285

10

EXECUTED GHERKIN STEP

When I follow the screen change's persistent registration link **PASS**

MedQAIR Technical file Technical file

Home > Demo Registered Device > Registration Back to the change

DR Registration Changed

Demo Registered Device · EUDAMED device registration · 65 of 65 answered · edits ride Change 7

1 answer changed — part of change [Change 7](#).

Not checked Check registration

EUDAMED, by hand

1 · Produce the package.
Check the current answers. Releasing the whole change records them before its EUDAMED XML can be generated. Use the action bar below to validate and complete these answers. After release, the same action prepares the XML download.

2 · A person uploads it to EUDAMED.
A person uploads the generated XML to EUDAMED; MDIS does not submit it.

3 · Compare with EUDAMED on demand.
Compare the stored device version with EUDAMED on demand.

Check EUDAMED now

1. Device Identification 13 / 13 · 1 answer changed

Device identification 13 questions

Which EU regulation Help

Progress

65 of 65 · XML needs all 65

In this change

Device Version
E2E-1788933787609 → Screen-registration-1788933808839

Released with Change 7. Registered answers stay until then.

Help

Each question shows EUDAMED's own guidance from its help button. The XML is produced here and uploaded to EUDAMED by hand; MDIS submits nothing itself.

Capture SHA-256: 1c099c8f232e3d3ab5dd56195d3b6ea0900edfad7b31ea2025a30173308998e2

11

EXECUTED GHERKIN STEP

And I restore the registration device version PASS

 **Technical file** 

   **[TEST] Flok Health EU** 
Manufacturer 

Check the current answers. Releasing the whole change records them before its EUDAMED XML can be generated. Use the action bar below to validate and complete these answers. After release, the same action prepares the XML download.

2 · A person uploads it to EUDAMED.
A person uploads the generated XML to EUDAMED; MDIS does not submit it.

3 · Compare with EUDAMED on demand.
Compare the stored device version with EUDAMED on demand.

[Check EUDAMED now](#)

1. Device identification
13 / 13

2. Markets & countries
4 / 4

3. Clinical / intended purpose
16 / 16

4. Risk class & rules
3 / 3

5. Sterilisation & safety
15 / 15

6. Certificates & UDI
14 / 14

Device identification
13 questions

Which EU regulation covers this device?
EUDAMED: applicable regulation

[Help](#) MDR (EU) 2017/745

Trade name
EUDAMED: device trade name - Annex VI A 2.1

[Help](#) Not asked — the controlling answer does not apply.

Basic UDI-DI
EUDAMED: Basic UDI-DI - Annex VI B 1

[Help](#) 099999999910W2

UDI-DI
EUDAMED: UDI-DI - Annex VI B 2

[Help](#) 09999999990007

Device Version
EUDAMED: device version

[Help](#) E2E-1788933787609

In this change

Nothing edited yet. Registered answers stay as they are.

Help

Each question shows EUDAMED's own guidance from its help button. The XML is produced here and uploaded to EUDAMED by hand; MDIS submits nothing itself.

Capture SHA-256: 93d38622ae5778a926ffebe0a1f8b18ffc18cb1c8daece65b22eab33b61138e8

MDIS walkthrough · 266 / 418

12

EXECUTED GHERKIN STEP

Then the restored answer survives reload without a field or change-card diff **PASS**

 Technical file ▼

  [TEST] Flok Health EU
Manufacturer ▼ 

Home › Demo Registered Device › Change 7

 **Change 7** Draft
follows 2.0.0 released 9 Sept

Discard draft Release

 **Documents** 3

 Add files

 **Drop PDFs here** · section guessed from the filename, you confirm

3 unchanged documents Show all

Ready to release? Ready

 **Every upload has a section.**
Settings / Review policy · Documents

 **Your representation for this market is confirmed.**
Who receives it · Release authority & reviewers

 **Registration** Unchanged
Registration matches the registered record.
Open registration

Who receives it Choose who
Nobody receives this release.

Capture SHA-256: 4504de6ab6fc40331e293b9592838bcdffcb370f2b97e450bf0d413ae136be45

13

EXECUTED GHERKIN STEP

When I follow the device registration fact to this exact draft PASS

 Technical file 

   [TEST] Flok Health EU
Manufacturer  

Home > Demo Registered Device > Registration

DR

Registration Unchanged

Demo Registered Device · EUDAMED device registration · 65 of 65 answered · edits ride Change 7

Not checked

Check registration

EUDAMED, by hand

1 · Produce the package.
Check the current answers. Releasing the whole change records them before its EUDAMED XML can be generated.
Use the action bar below to validate and complete these answers. After release, the same action prepares the XML download.

2 · A person uploads it to EUDAMED.
A person uploads the generated XML to EUDAMED; MDIS does not submit it.

3 · Compare with EUDAMED on demand.
Compare the stored device version with EUDAMED on demand.

Check EUDAMED now

1. Device identification
13 / 13

2. Markets & countries
4 / 4

3. Clinical / intended

Device identification 13 questions

Which EU regulation covers this device?  Help

EUDAMED: applicable regulation

MDR (EU) 2017/745

Progress

65 of 65 · XML needs all 65

In this change

Nothing edited yet. Registered answers stay as they are.

Help

Each question shows EUDAMED's own guidance from its help button. The XML is produced here and uploaded to EUDAMED by hand; MDIS submits nothing itself.

Capture SHA-256: 283ae004ad603dd6e812c8d8441ac798f38a5a866b93405e2c3ff472c9122c43

MDIS walkthrough · 268 / 418

14

EXECUTED GHERKIN STEP

Then the registration entry point retains this device and release **PASS***No visible change at this step; the asserted UI state remains visible*

 **Technical file** 

   **[TEST] Flok Health EU** 
Manufacturer 

Home > Demo Registered Device > Registration

DR **Registration** Unchanged

Demo Registered Device · EUDAMED device registration · 65 of 65 answered · edits ride Change 7

Not checked Check registration

EUDAMED, by hand

1 · Produce the package.
Check the current answers. Releasing the whole change records them before its EUDAMED XML can be generated.
Use the action bar below to validate and complete these answers. After release, the same action prepares the XML download.

2 · A person uploads it to EUDAMED.
A person uploads the generated XML to EUDAMED; MDIS does not submit it.

3 · Compare with EUDAMED on demand.
Compare the stored device version with EUDAMED on demand.

Check EUDAMED now

1. Device identification
13 / 13

2. Markets & countries
4 / 4

3. Clinical / intended

Device identification 13 questions

Which EU regulation covers this device?  Help MDR (EU) 2017/745

EUDAMED: applicable regulation

Progress



65 of 65 · XML needs all 65

In this change

Nothing edited yet. Registered answers stay as they are.

Help

Each question shows EUDAMED's own guidance from its help button. The XML is produced here and uploaded to EUDAMED by hand; MDIS submits nothing itself.

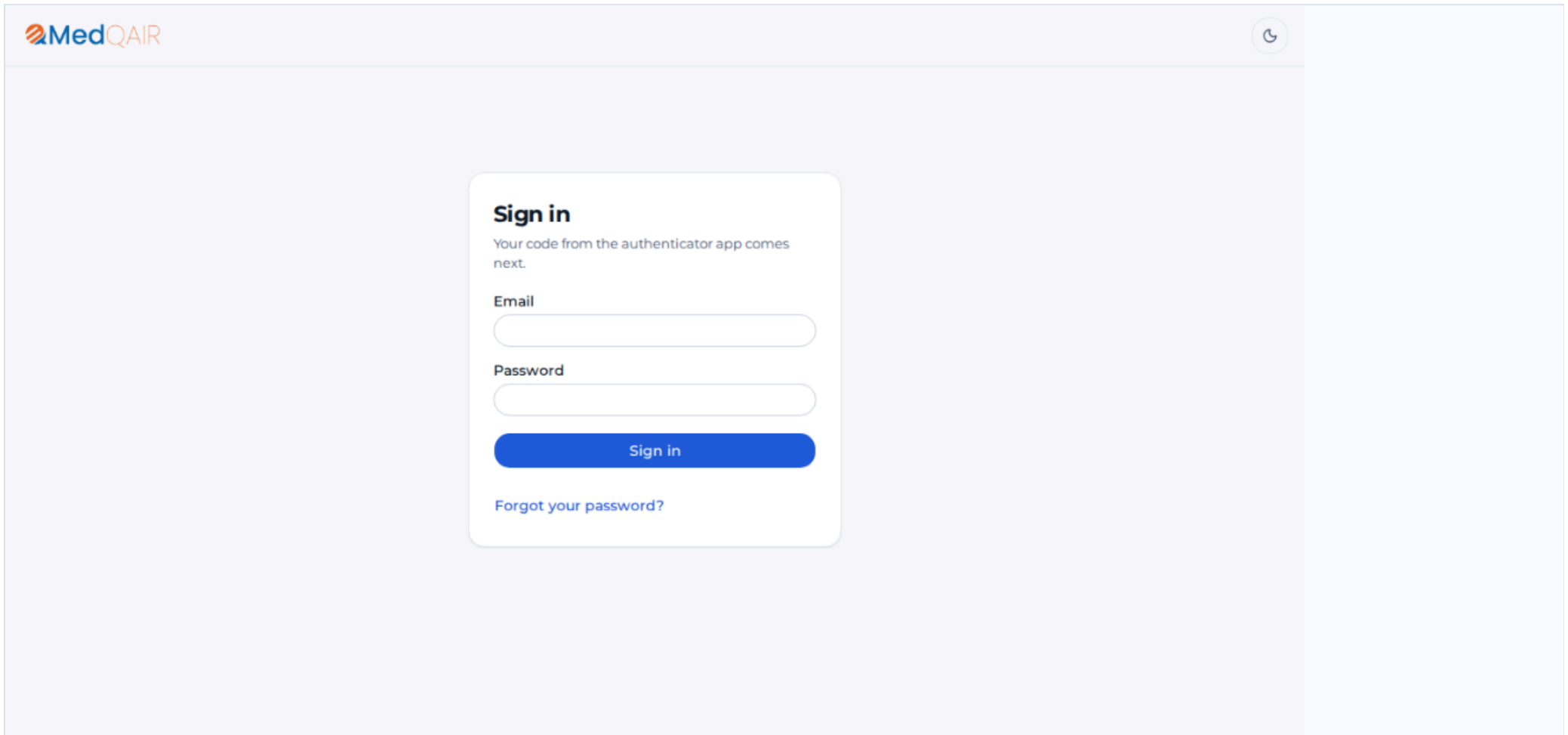
Capture SHA-256: 283ae004ad603dd6e812c8d8441ac798f38a5a866b93405e2c3ff472c9122c43

A released registration offers XML and a readable summary of the same snapshot

01

EXECUTED GHERKIN STEP

Given the redesign sign-in page **PASS**



Capture SHA-256: 953d9a1220a1b501a0ede3a87b7d5516c6552f0e0d727f3b59246c01ef255e3b

02

EXECUTED GHERKIN STEP

When I sign in to the redesign as the EU manufacturer PASS

 Technical file 

   [TEST] Flok Health EU
Manufacturer  

Your work

[TEST] Flok Health EU - Wednesday 9 September

 **5**
drafts to finish

 **0**
returned for changes

 **0**
waiting on a partner

 **16**
devices, 12 released

Needs you5 drafts

 **VitaPulse Monitor**
E2E portfolio VitaPulse Monitor registration draft · 2.0

Continue

 **Flok Posture Coach**
1.0 first release

Continue

 **E2E Journey Device 1788933721006342**
Change 2

Continue

 **E2E Journey Device 1788933770899946**
2 open drafts · Change 3

Continue

Devices · 16All 16 >

 **Flok Health**Unreleased

 **Demo Registered Device**
2.0.0 released 9 SeptReleased

 **SecurView DX**
1.0 released 9 SeptReleased

 **AeroVent Home**
1.0 released 9 SeptReleased

 **OrthoFix Pro**
1.0 released 9 SeptReleased

 **VitaPulse Monitor**

Capture SHA-256: 241514f5cc424e915d839e844265f7671c8cb008bc34a006641154eb02e70483

03

EXECUTED GHERKIN STEP

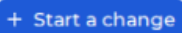
And I open the seeded registered device PASS

 Technical file 

   [TEST] Flok Health EU
Manufacturer  

Home › Devices › Demo Registered Device

 **Demo Registered Device** Released
current 2.0.0 released 9 Sept · Basic UDI-DI 099999999910W2

Choose who 

Changes and releases

Release history

 **2.0.0**
Released 9 Sept · Change 3

 **2.0.0**
Released 9 Sept · Change 2

 **Demo registered baseline**
Released 9 Sept

Delivered

Open

Delivered

Open

Delivered

Open

Current file 2.0.0 · 3 documents

Find

 **Technical documentation** 2 documents

happy-path-annex-vi-dataset.pdf

happy-path-annex-vi-dataset.pdf

 **Certificates & declarations** 1 document

Registration Open

Loading...

Who can open it Choose who

Only you, so far.

Identification

UDI-DI
09999999990007

Basic UDI-DI
099999999910W2

UDI-PI
—

Capture SHA-256: eb6501a09c2ccdb288c781145892953481755e6f070796de590d36404acce752

MDIS walkthrough · 272 / 418

04

EXECUTED GHERKIN STEP

And I start a correlation release from the device PASS

 Technical file ▼

🔄 TF [TEST] Flok Health EU ▼ EE
Manufacturer

Home › Demo Registered Device › Change 8

DR **Change 8** Draft

Version E2E-registration-correlation-1788933813013 follows 2.0.0 released 9 Sept Rename

📄 **Documents** 3 Find 📁 Add files

📁 Drop PDFs here · section guessed from the filename, you confirm

3 unchanged documents Show all

Ready to release? Ready

✓ **Every upload has a section.**
Settings / Review policy · Documents

✓ **Your representation for this market is confirmed.**
Who receives it · Release authority & reviewers

🌐 **Registration** Unchanged
Registration matches the registered record.
Open registration

Who receives it Choose who
Nobody receives this release.

Capture SHA-256: 91b828f9e5c6fd275902943a08666d6ba580a3d6b70e83e9a4acc8765e7a91fd

05

EXECUTED GHERKIN STEP

And I follow the screen change's persistent registration link PASS

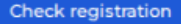
 Technical file 

   [TEST] Flok Health EU
Manufacturer  

Home > Demo Registered Device > Registration

 **Registration** Unchanged

Demo Registered Device · EUDAMED device registration · 65 of 65 answered · edits ride Change 8

Not checked  

EUDAMED, by hand

1 · Produce the package.
Check the current answers. Releasing the whole change records them before its EUDAMED XML can be generated.
Use the action bar below to validate and complete these answers. After release, the same action prepares the XML download.

2 · A person uploads it to EUDAMED.
A person uploads the generated XML to EUDAMED; MDIS does not submit it.

3 · Compare with EUDAMED on demand.
Compare the stored device version with EUDAMED on demand.




65 of 65 · XML needs all 65

In this change

Nothing edited yet. Registered answers stay as they are.

Help

Each question shows EUDAMED's own guidance from its help button. The XML is produced here and uploaded to EUDAMED by hand; MDIS submits nothing itself.

 13 / 13

 4 / 4



Device identification 13 questions

Which EU regulation covers this device?  

EUDAMED: applicable regulation

Capture SHA-256: 159a89f12afae911ed68019df2fb3eedad5d2735d0f77d6b249aadd0032595b3

06

EXECUTED GHERKIN STEP

And I save this screen release's production version **PASS**

 **Technical file** 

   **[TEST] Flok Health EU** 
Manufacturer 

Check the current answers. Releasing the whole change records them before its EUDAMED XML can be generated. Use the action bar below to validate and complete these answers. After release, the same action prepares the XML download.

2 · A person uploads it to EUDAMED.
A person uploads the generated XML to EUDAMED; MDIS does not submit it.

3 · Compare with EUDAMED on demand.
Compare the stored device version with EUDAMED on demand.

[Check EUDAMED now](#)

1. Device identification
13 / 13 · 1 answer changed

2. Markets & countries
4 / 4

3. Clinical / intended purpose
16 / 16

4. Risk class & rules
3 / 3

5. Sterilisation & safety
15 / 15

6. Certificates & UDI
14 / 14

Device identification 13 questions

Which EU regulation covers this device?  [Help](#)

MDR (EU) 2017/745

EUDAMED: applicable regulation

Trade name  [Help](#)

Not asked — the controlling answer does not apply.

EUDAMED: device trade name · Annex VI A 2.1

Basic UDI-DI  [Help](#)

099999999910W2

EUDAMED: Basic UDI-DI · Annex VI B 1

UDI-DI  [Help](#)

09999999990007

EUDAMED: UDI-DI · Annex VI B 2

Device Version  [Help](#)

E2E-registration-correlation-178893381301

EUDAMED: device version

Device version
E2E-1788933787609 → E2E-registration-correlation-1788933813013

Released with Change 8. Registered answers stay until then.

Help

Each question shows EUDAMED's own guidance from its help button. The XML is produced here and uploaded to EUDAMED by hand; MDIS submits nothing itself.

Capture SHA-256: 06e59fef1b412884924123e9c13820a56b36abee07aae7c373af1b419ac52e81

07

EXECUTED GHERKIN STEP

And I answer the market questions the release still needs PASS

 **Technical file** 

   **[TEST] Flok Health EU** 
Manufacturer 

Check the current answers. Releasing the whole change records them before its EUDAMED XML can be generated. Use the action bar below to validate and complete these answers. After release, the same action prepares the XML download.

2 · A person uploads it to EUDAMED.
A person uploads the generated XML to EUDAMED; MDIS does not submit it.

3 · Compare with EUDAMED on demand.
Compare the stored device version with EUDAMED on demand.

[Check EUDAMED now](#)

1. Device identification
13 / 13 · 1 answer changed

2. Markets & countries
4 / 4

3. Clinical / intended purpose
16 / 16

4. Risk class & rules
3 / 3

5. Sterilisation & safety
15 / 15

6. Certificates & UDI
14 / 14

Markets & countries 4 questions

Countries where the device is placed on the market 

EUDAMED: Member States where the device is made available
· Annex VI A 2.4

AT BE BG HR CY CZ

DE DK EE EL ES FI FR

HU IE IT LT LU LV MT

NL PL PT RO SE SI SK

Languages the instructions for use are provided in 

EUDAMED: IFU languages

—

What is the EU market status of this UDI-DI? 

EUDAMED: UDI-DI market status
· Annex VI B 2.4

No longer placed on the EU market

Not intended for the EU market

On the EU market

Device version
E2E-1788933787609 → E2E-registration-correlation-1788933813013

Released with Change 8. Registered answers stay until then.

Help
Each question shows EUDAMED's own guidance from its help button. The XML is produced here and uploaded to EUDAMED by hand; MDIS submits nothing itself.

Capture SHA-256: 0a8173a989aa9bb7082e6741d5c0093846bff6fd5f5f5c65d08ea6cff740ab0c

08

EXECUTED GHERKIN STEP

And I check the registration **PASS**

 Technical file 

 [TEST] Flok Health EU
Manufacturer 

Home > Demo Registered Device > Registration

DR **Registration** Changed

Demo Registered Device · EUDAMED device registration · 65 of 65 answered · edits ride Change 8

1 answer changed — part of change [E2E-registration-correlation-1788933813013](#).

Not checked Checking...

EUDAMED, by hand

1 · Produce the package.
Check the current answers. Releasing the whole change records them before its EUDAMED XML can be generated.
Use the action bar below to validate and complete these answers. After release, the same action prepares the XML download.

2 · A person uploads it to EUDAMED.
A person uploads the generated XML to EUDAMED; MDIS does not submit it.

3 · Compare with EUDAMED on demand.
Compare the stored device version with EUDAMED on demand.

Check EUDAMED now

1. Device identification
13 / 13 · 1 answer changed

Markets & countries 4 questions

Countries where the [Help](#)

Progress



65 of 65 · XML needs all 65

In this change

Device Version
E2E-1788933787609 → E2E-registration-correlation-1788933813013

Released with Change 8. Registered answers stay until then.

Help

Each question shows EUDAMED's own guidance from its help button. The XML is produced here and uploaded to EUDAMED by hand; MDIS submits nothing itself.

Capture SHA-256: 5f9897c9dca8329130889ac8fc57ebbe423927b404634c5146bc7e4f26257f45

09

EXECUTED GHERKIN STEP

Then the registration is ready for release **PASS**

 Technical file 

   [TEST] Flok Health EU
Manufacturer 

Home > Demo Registered Device > Registration

DR **Registration** 

Demo Registered Device · EUDAMED device registration · 65 of 65 answered · edits ride Change 8

Back to the change

1 answer changed — part of change [E2E-registration-correlation-1788933813013](#).

Ready for release Registration is ready for release. 

EUDAMED, by hand

1 · Produce the package.
Check the current answers. Releasing the whole change records them before its EUDAMED XML can be generated.
Use the action bar below to validate and complete these answers. After release, the same action prepares the XML download.

2 · A person uploads it to EUDAMED.
A person uploads the generated XML to EUDAMED; MDIS does not submit it.

3 · Compare with EUDAMED on demand.
Compare the stored device version with EUDAMED on demand.


Progress



65 of 65 · XML needs all 65

In this change

Device Version
E2E-1788933787609 → E2E-registration-correlation-1788933813013

Released with Change 8. Registered answers stay until then.

Help

Each question shows EUDAMED's own guidance from its help button. The XML is produced here and uploaded to EUDAMED by hand; MDIS submits nothing itself.

1. Device identification
13 / 13 · 1 answer changed

Markets & countries 4 questions

Countries where the 

Capture SHA-256: 4211ab11b4aa99046733e1d82b3500d014f7be2e4b9d7cf8485b8ba8e883df43

10

EXECUTED GHERKIN STEP

When I follow the editor back to its change PASS

The screenshot displays the MedQAIR 'Technical file' interface. At the top, the MedQAIR logo is on the left, and a 'Technical file' dropdown menu is next to it. On the right, there are icons for a refresh, a 'TF' (Technical File) status, and a dropdown menu showing '[TEST] Flok Health EU' with 'Manufacturer' below it. A blue circular icon with 'EE' is also present.

The main content area shows a breadcrumb trail: 'Home > Demo Registered Device > Change 8'. Below this, the title 'Change 8' is displayed with a 'Draft' status. A green 'DR' icon is to the left of the title. Below the title, the version 'E2E-registration-correlation-1788933813013' is shown, followed by 'follows 2.0.0 released 9 Sept' and a 'Rename' link.

On the right side of the main content area, there are two buttons: 'Discard draft' and 'Release'.

The left sidebar contains a 'Documents' section with a count of '3'. It includes a 'Find' input field and an 'Add files' button. Below this is a dashed box with the text 'Drop PDFs here · section guessed from the filename, you confirm'. At the bottom of the sidebar, it says '3 unchanged documents' and a 'Show all' link.

The right sidebar has three sections:

- Ready to release?** with a 'Ready' status. It contains two items, each with a green checkmark:
 - 'Every upload has a section.' with subtext 'Settings / Review policy · Documents'.
 - 'Your representation for this market is confirmed.' with subtext 'Who receives it · Release authority & reviewers'.
- Registration** with a 'Changed' status. It states '1 answer differs from the registered record.' and includes a button '> Show 1 registration change' and an 'Open registration' button.
- Who receives it** with a 'Choose who' status.

Capture SHA-256: 51503ba19a30e8274dbbaa6a0159c3542e5fca2dd1a1685ac19e8b7a53f81106

11

EXECUTED GHERKIN STEP
And I release the change PASS

 Technical file ▼

 [TEST] Flok Health EU
Manufacturer ▼



Home › Demo Registered Device › Change 8

DR

Change 8

Draft

Version E2E-registration-correlation-1788933813013 follows 2.0.0 released 9 Sept [Rename](#)

 Documents 3

 Add files

 Drop PDFs here · section guessed from the filename, you confirm

3 unchanged documents [Show all](#)

Ready to release?

Ready

✓ Every upload has a section.
Settings / Review policy · Documents

✓ Your representation for this market is confirmed.
Who receives it · Release authority & reviewers

 Registration

Changed

1 answer differs from the registered record.

> Show 1 registration change

Open registration

Who receives it

Choose who

Capture SHA-256: 871f76b8ca33acb6468e9056677bd15c7793fcc4c60b18bbf1b0f408342f6764

MDIS walkthrough · 280 / 418

12

EXECUTED GHERKIN STEP

Then the release is delivered immediately **PASS**

 Technical file 

  [TEST] Flok Health EU
Manufacturer  

Home > Demo Registered Device > Change 8

Delivered to the frozen recipient set

 **Change 8** 

Version **E2E-registration-correlation-1788933813013** on the market since 9 Sept

 **Documents** 3 · frozen as released

3 unchanged documents

[Show all](#)

 **Registration** 

1 answer differs from the registered record.

[> Show 1 registration change](#)

[Open registration](#)

Who receives it Choose who

Nobody receives this release.

 **Delivery**

Delivered on 2026-09-09.

Summary

Version	Documents
E2E-registration-	3

Capture SHA-256: 1aaff6c740ecba0874fe33f762df60f878422650b88b9dc7797254660852843e

13

EXECUTED GHERKIN STEP

When I follow the screen change's persistent registration link **PASS**

 Technical file 

 TF [TEST] Flok Health EU  EE
Manufacturer

Home > Demo Registered Device > Registration Back to the change

DR **Registration** Changed
Demo Registered Device · EUDAMED device registration · 65 of 65 answered · edits ride Change 8

1 answer changed — part of change [E2E-registration-correlation-1788933813013](#).

Released EUDAMED record
Generate the XML from the registration included in this released change. [Generate EUDAMED XML](#)

EUDAMED, by hand
1 · Produce the package.
The released registration can produce the EUDAMED XML package.
Use the action bar below to validate and complete these answers. After release, the same action prepares the XML download.
2 · A person uploads it to EUDAMED.
A person uploads the generated XML to EUDAMED; MDIS does not submit it.
3 · Compare with EUDAMED on demand.
Compare the stored device version with EUDAMED on demand.
[Check EUDAMED now](#)

1. Device identification
13 / 13 · 1 answer changed

Answers are read-only — this release has moved past draft. Start a change to edit them.

Progress

65 of 65 · XML needs all 65

In this change
Device Version
E2E-1788933787609 → E2E-registration-correlation-1788933813013
Released with Change 8. Registered answers stay until then.

Help
Each question shows EUDAMED's own guidance from its help button. The XML is produced here and uploaded to EUDAMED by hand; MDIS submits nothing itself.

Capture SHA-256: 01bcc9e7af317f9711388ec3139df37f159d48dbd722a3bc6c85d1da0cb9cc1d

14

EXECUTED GHERKIN STEP

Then the registration entry point retains this device and release **PASS***No visible change at this step; the asserted UI state remains visible*

MedQAIR Technical file [TEST] Flok Health EU Manufacturer

Home > Demo Registered Device > Registration

Registration Changed

Demo Registered Device · EUDAMED device registration · 65 of 65 answered · edits ride Change 8

1 answer changed — part of change [E2E-registration-correlation-1788933813013](#).

Released EUDAMED record
Generate the XML from the registration included in this released change. [Generate EUDAMED XML](#)

EUDAMED, by hand

1 · Produce the package.
The released registration can produce the EUDAMED XML package.
Use the action bar below to validate and complete these answers. After release, the same action prepares the XML download.

2 · A person uploads it to EUDAMED.
A person uploads the generated XML to EUDAMED; MDIS does not submit it.

3 · Compare with EUDAMED on demand.
Compare the stored device version with EUDAMED on demand.
[Check EUDAMED now](#)

Progress
65 of 65 · XML needs all 65

In this change

Device Version
E2E-1788933787609 → E2E-registration-correlation-1788933813013

Released with Change 8. Registered answers stay until then.

Help
Each question shows EUDAMED's own guidance from its help button. The XML is produced here and uploaded to EUDAMED by hand; MDIS submits nothing itself.

1. Device identification 13 / 13 · 1 answer changed

Answers are read-only — this release has moved past draft. Start a change to edit them.

Capture SHA-256: 01bcc9e7af317f9711388ec3139df37f159d48dbd722a3bc6c85d1da0cb9cc1d

15

EXECUTED GHERKIN STEP

When I download the screen registration XML and readable summary PASS

 Technical file 

 TF [TEST] Flok Health EU
Manufacturer  EE

Home > Demo Registered Device > Registration Back to the change

DR

Registration Changed

Demo Registered Device · EUDAMED device registration · 65 of 65 answered · edits ride Change 8

1 answer changed — part of change [E2E-registration-correlation-1788933813013](#).

Released EUDAMED record
Generate the XML from the registration included in this released change.

[Download XML](#) [Download summary](#)

EUDAMED, by hand

1 · Produce the package.
The released registration can produce the EUDAMED XML package.
Use the action bar below to validate and complete these answers. After release, the same action prepares the XML download.

2 · A person uploads it to EUDAMED.
A person uploads the generated XML to EUDAMED; MDIS does not submit it.

3 · Compare with EUDAMED on demand.
Compare the stored device version with EUDAMED on demand.
[Check EUDAMED now](#)

1. Device identification
13 / 13 · 1 answer changed

Answers are read-only — this release has moved past draft. Start a change to edit them.

Progress

65 of 65 · XML needs all 65

In this change

Device Version
E2E-1788933787609 → E2E-registration-correlation-1788933813013

Released with Change 8. Registered answers stay until then.

Help

Each question shows EUDAMED's own guidance from its help button. The XML is produced here and uploaded to EUDAMED by hand; MDIS submits nothing itself.

Capture SHA-256: 01807f67508720511799faab180855a2f1e4e1184e45887c4b39d0d24be4c3d9

16

EXECUTED GHERKIN STEP

Then both screen package files describe the exact frozen registration **PASS***No visible change at this step; the asserted UI state remains visible*

MedQAIR Technical file [TEST] Flok Health EU Manufacturer

Home > Demo Registered Device > Registration

Registration Changed

Demo Registered Device · EUDAMED device registration · 65 of 65 answered · edits ride Change 8

Back to the change

1 answer changed — part of change [E2E-registration-correlation-1788933813013](#).

Released EUDAMED record
Generate the XML from the registration included in this released change. [Download XML](#) [Download summary](#)

EUDAMED, by hand

1 · Produce the package.
The released registration can produce the EUDAMED XML package.
Use the action bar below to validate and complete these answers. After release, the same action prepares the XML download.

2 · A person uploads it to EUDAMED.
A person uploads the generated XML to EUDAMED; MDIS does not submit it.

3 · Compare with EUDAMED on demand.
Compare the stored device version with EUDAMED on demand.

[Check EUDAMED now](#)

1. Device identification
13 / 13 · 1 answer changed

Answers are read-only — this release has moved past draft. Start a change to edit them.

Progress
65 of 65 · XML needs all 65

In this change

Device Version
E2E-1788933787609 → E2E-registration-correlation-1788933813013

Released with Change 8. Registered answers stay until then.

Help
Each question shows EUDAMED's own guidance from its help button. The XML is produced here and uploaded to EUDAMED by hand; MDIS submits nothing itself.

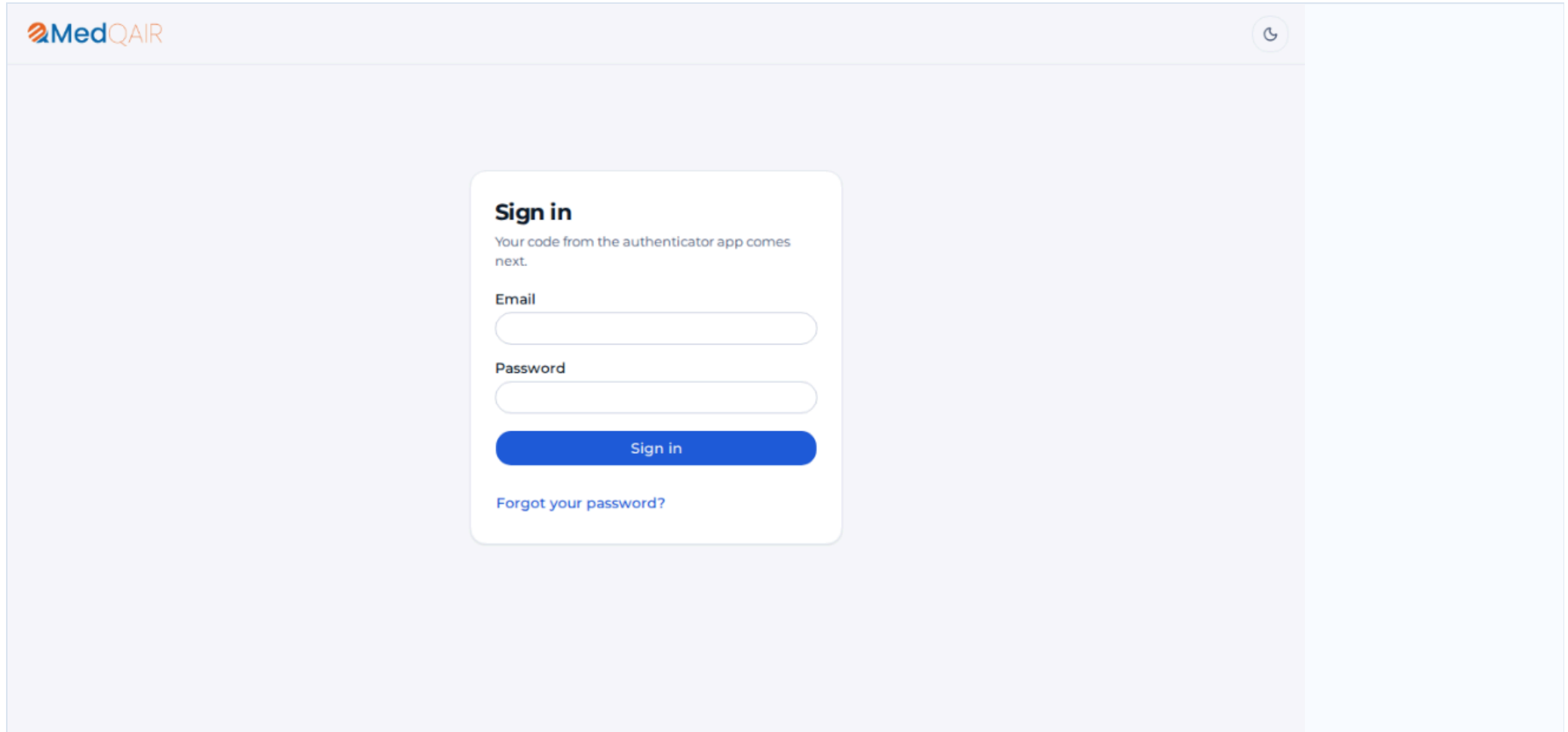
Capture SHA-256: 01807f67508720511799faab180855a2f1e4e1184e45887c4b39d0d24be4c3d9

A released device remains released after its history crosses a page boundary

01

EXECUTED GHERKIN STEP

Given the redesign sign-in page **PASS**



Capture SHA-256: 953d9a1220a1b501a0ede3a87b7d5516c6552f0e0d727f3b59246c01ef255e3b

02

EXECUTED GHERKIN STEP

When I sign in to the redesign as the EU manufacturer PASS

 Technical file 

   [TEST] Flok Health EU Manufacturer  

Your work

[TEST] Flok Health EU - Wednesday 9 September

 **5**
drafts to finish

 **0**
returned for changes

 **0**
waiting on a partner

 **18**
devices, 12 released

+ Add a device

Needs you

5 drafts

 **VitaPulse Monitor**
E2E portfolio VitaPulse Monitor registration draft · 2.0

Continue

 **Flok Posture Coach**
1.0 first release

Continue

 **E2E Journey Device 1788933721006342**
Change 2

Continue

 **E2E Journey Device 1788933770899946**
2 open drafts · Change 3

Continue

Devices · 18

All 18 >

 **Flok Health**

Unreleased

 **Demo Registered Device**
2.0.0 released 9 Sept

Released

 **AeroVent Home**
1.0 released 9 Sept

Released

 **OrthoFix Pro**
1.0 released 9 Sept

Released

 **VitaPulse Monitor**
1.0 released 9 Sept · E2E portfoli...

Released

 **DemoSage Lite**

Capture SHA-256: 7a5b8747b89442ef37cbf956a7c4953b9b50c29d7e8287fcc7141dcbcfb6825a

03

EXECUTED GHERKIN STEP

And I create a run-owned pagination release-history device PASS

 Technical file 

  [TEST] Flok Health EU
Manufacturer  

Home › Devices › E2E Pagination Release History 1788933869676-240d6e19

 **E2E Pagination Release History 1788933869676-240d6e19** Unreleased
not released yet · Basic UDI-DI —Choose who  Start first release**Changes and releases**

No changes yet.

Registration Open

Not started. EUDAMED needs every answer.

Who can open it Choose who

Only you, so far.

IdentificationUDI-DI
PG-1788933869676-240d6e19Basic UDI-DI
—UDI-PI
—

Capture SHA-256: 0e558dade13726ef0598b204bdd58d508b3990144e1a608699ce3f899676bd2d

04

EXECUTED GHERKIN STEP

And I start production version "1.0 pagination baseline" PASS

The screenshot displays the MedQAIR web application interface. At the top, the MedQAIR logo is on the left, followed by a 'Technical file' dropdown. On the right, there are icons for a refresh, a 'TF' tag, a dropdown menu showing '[TEST] Flok Health EU Manufacturer', and a user profile icon 'EE'.

The main content area shows a breadcrumb trail: 'Home > E2E Pagination Release History 1788933869676-240d6e19 > Change 1'. Below this, the title 'Change 1' is followed by a 'Draft' status and a 'Rename' link. Underneath, it says 'Version 1.0 pagination baseline' with another 'Rename' link.

On the right side of the main area, there are two buttons: 'Discard draft' and 'Release'.

Below the title, there is a 'Documents' section with a 'Find' input field and an 'Add files' button. A dashed box indicates where to 'Drop PDFs here', with a note: 'section guessed from the filename, you confirm'. Below this, it states 'No documents yet.'

On the far right, a 'Ready to release?' sidebar is visible, featuring a 'Ready' status. It contains two items:

- A green checkmark icon followed by the text: 'Every upload has a section. Settings / Review policy · Documents'.
- A yellow warning triangle icon followed by the text: 'This device's target market is not recorded — add its EUDAMED registration from the device's Registration page; the registration records the market.' Below this, it says: 'Who receives it · Release authority & reviewers · recommended — you can still release'. Further down, it explains: 'MDIS compares your organisation's country (from its SRN) with this device's market. Your representative is appointed under Who receives it — a partner you are already connected to at once, a new one once they accept the invitation. Confirming records that the appointment covers this market.' At the bottom of this item is a link: 'Open Who receives it'.

Capture SHA-256: 85dd691932aaaf375df8460e6efc4bfab9aa4d87b2e01aa55b6bcdeb8850ff48

05

EXECUTED GHERKIN STEP

And I upload a document to the change PASS

 Technical file 

  [TEST] Flok Health EU
Manufacturer 

Home › E2E Pagination Release History 1788933869676-240d6e19 › Change 1

 **Change 1** Draft

Version 1.0 pagination baseline [Rename](#)

 **Documents** 1 · 1 changed

 Add files

 Drop PDFs here · section guessed from the filename, you confirm

 IFU & labelling

1 document

☐

multi-eo-product-label.pdf

New

 ...

Ready to release? Ready

 Every upload has a section.
Settings / Review policy · Documents

 This device's target market is not recorded — add its EUDAMED registration from the device's Registration page; the registration records the market.

Who receives it · Release authority & reviewers · recommended — you can still release

MDIS compares your organisation's country (from its SRN) with this device's market. Your representative is appointed under Who receives it — a partner you are already connected to at once, a new one once they accept the invitation. Confirming records that the appointment covers this market.

[Open Who receives it](#)

Capture SHA-256: 96954ff2f3f765fd4e0005df12ba91216ef786e5ab93fdb6ae934e837a28e373

06

EXECUTED GHERKIN STEP

And I complete the release's market facts PASS

 Technical file 

  [TEST] Flok Health EU
Manufacturer  

Home > E2E Pagination Release History 1788933869676-240d6e19 > Change 1

 **Change 1** Draft

Version 1.0 pagination baseline Rename

 **Documents** 1 · 1 changed

 Add files

 Drop PDFs here · section guessed from the filename, you confirm

 IFU & labelling

1 document

☐

multi-eo-product-label.pdf

New

 ...

Ready to release? Ready

 Every upload has a section.
Settings / Review policy · Documents

 Your representation for this market is confirmed.
Who receives it · Release authority & reviewers

 **Registration** Incomplete

33 of 65 answers · EUDAMED XML needs all 65 · not needed to release

Answer remaining 32

Open registration

Who receives it Choose who

Capture SHA-256: 9e738bd4cb14f33b96c42d91816ecba21c1b837d359def76a05dc4389d82cdd0

07

EXECUTED GHERKIN STEP

And I press Release once **PASS**

 **Technical file** 

  **[TEST] Flok Health EU** 
Manufacturer 

Home > E2E Pagination Release History 1788933869676-240d6e19 > Change 1

 **Change 1** Draft

Version 1.0 pagination baseline Rename

 **Documents** 1 · 1 changed

 **Add files**

 **Drop PDFs here** · section guessed from the filename, you confirm

 **IFU & labelling**

1 document

☐

multi-eo-product-label.pdf

New

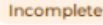
Ready to release?



 **Every upload has a section.**
Settings / Review policy · Documents

 **Your representation for this market is confirmed.**
Who receives it · Release authority & reviewers

 **Registration**



33 of 65 answers · EUDAMED XML needs all 65 · not needed to release

Answer remaining 32

Open registration

Who receives it

Choose who

Capture SHA-256: 5b835bbe4b7a887082456eabc2fccf42b3d6c3958c4e40a614c8e512f63195e

08

EXECUTED GHERKIN STEP

Then the release is delivered immediately PASS

 **Technical file** 

  **[TEST] Flok Health EU** 
Manufacturer 

Home > E2E Pagination Release History 1788933869676-240d6e19 > Change 1

 **Change 1** Delivered

Version 1.0 pagination baseline on the market since 9 Sept

 **Documents** 1 · 1 changed · frozen as released

 **IFU & labelling**

1 document

 multi-eo-product-label.pdf

New

 **Registration** Incomplete

33 of 65 answers · EUDAMED XML needs all 65 · not needed to release

Answer remaining 32

Open registration

Who receives it Choose who

Nobody receives this release.

 **Delivery**

Delivered on 2026-09-09.

Summary

Version

1.0 pagination

Documents

1

Capture SHA-256: 6336a105ceb71d6dbd6446663928e616a64c20a3b14e6cf81cf9da8664aa0027

09

EXECUTED GHERKIN STEP

When I seed ten newer pagination release-history drafts PASS

The released baseline remains visible while ten newer drafts are created through the API for the pagination check.

 Technical file 

  [TEST] Flok Health EU
Manufacturer 

Home › E2E Pagination Release History 1788933869676-240d6e19 › Change 1

Delivered to the frozen recipient set

 **Change 1** Delivered
Version 1.0 pagination baseline on the market since 9 Sept

 **Documents** 1 · 1 changed · frozen as released

 **IFU & labelling** 1 document

 multi-eo-product-label.pdf  ...
New

 **Registration** Incomplete
33 of 65 answers · EUDAMED XML needs all 65 · not needed to release
Answer remaining 32
Open registration

Who receives it Choose who
Nobody receives this release.

 **Delivery**
Delivered on 2026-09-09.

Summary

Version	Documents
1.0 pagination	1

Capture SHA-256: 6336a105ceb71d6dbd6446663928e616a64c20a3b14e6cf81cf9da8664aa0027

10

EXECUTED GHERKIN STEP

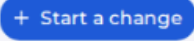
And I open the run-owned pagination release-history device PASS

 Technical file 

   [TEST] Flok Health EU
Manufacturer  

Home > Devices > E2E Pagination Release History 1788933869676-240d6e19

 **E2E Pagination Release History 1788933869676-240d6e19** Released
current 1.0 pagination baseline released 9 Sept · pagination newer draft 10 cab738c9-6760-46b9-9de6-8c2f4804f41a in draft · Basic UDI-DI E2EBASIC1788933871834411

Choose who 

Changes and releases	Release history
 pagination newer draft 10 cab738c9-6760-46b9-9de6-8c2f4804f41a Draft · documents only	Draft Continue
 pagination newer draft 9 43ada0ba-d1a8-42ff-b8f6-73f9d5efd060 Draft · documents only	Draft Continue
 pagination newer draft 8 3ccce879-2abb-4aa6-b111-327190c22e7b Draft · documents only	Draft Continue
 pagination newer draft 7 7972174d-20c6-4fb1-ba28-eb617386e7d2 Draft · documents only	Draft Continue
 pagination newer draft 6 391e04e1-e8ca-4070-95ec-92acf2f84817 Draft · documents only	Draft Continue
 pagination newer draft 5 086487d6-03e3-44ca-b5a5-6bc7953ab808 Draft · documents only	Draft Continue
 pagination newer draft 4 0f354a8f-a840-4648-94a0-101dfbd09805 Draft · documents only	Draft Continue

Registration Open
33 of 65 answers · EUDAMED XML needs all 65

Who can open it Choose who
Only you, so far.

Identification
UDI-DI
PG-1788933869676-240d6e19

Basic UDI-DI
E2EBASIC1788933871834411

UDI-PI
-

Capture SHA-256: bb14a74f16907e52ce42f9b61ed81431c51efc13956820753505dec70c474929

11

EXECUTED GHERKIN STEP

Then the released market identity survives paginated release history

PASS

The device page was reloaded and retains its released market identity while the observed history crosses two cursor pages.

MedQAIR

Technical file

TF

[TEST] Flok Health EU

Manufacturer

EE

Home > Devices > E2E Pagination Release History 1788933869676-240d6e19

EP

E2E Pagination Release History 1788933869676-240d6e19

Released

current 1.0 pagination baseline released 9 Sept · pagination newer draft 10 cab738c9-6760-46b9-9de6-8c2f4804f41a in draft · Basic UDI-DI E2EBASIC1788933871834411

Choose who

+ Start a change

Changes and releases

Release history

pagination newer draft 10 cab738c9-6760-46b9-9de6-8c2f4804f41a

Draft · documents only

Draft

Continue

pagination newer draft 9 43ada0ba-d1a8-42ff-b8f6-73f9d5efd060

Draft · documents only

Draft

Continue

pagination newer draft 8 3ccce879-2abb-4aa6-b111-327190c22e7b

Draft · documents only

Draft

Continue

pagination newer draft 7 7972174d-20c6-4fb1-ba28-eb617386e7d2

Draft · documents only

Draft

Continue

pagination newer draft 6 391e04e1-e8ca-4070-95ec-92acf2f84817

Draft · documents only

Draft

Continue

pagination newer draft 5 086487d6-03e3-44ca-b5a5-6bc7953ab808

Draft · documents only

Draft

Continue

pagination newer draft 4 0f354a8f-a840-4648-94a0-101dfbd09805

Draft · documents only

Draft

Continue

Registration

Open

33 of 65 answers · EUDAMED XML needs all 65

Who can open it

Choose who

Only you, so far.

Identification

UDI-DI

PG-1788933869676-240d6e19

Basic UDI-DI

E2EBASIC1788933871834411

UDI-PI

-

Capture SHA-256: bb14a74f16907e52ce42f9b61ed81431c51efc13956820753505dec70c474929

features/cross-cutting/screen-platform-admin-wave2.feature · @MODULE:PLATFORM-ADMIN @SR-012

PASS

the exact admin entry remains system-scoped while current UI renders Operations

This proves the current access boundary. The entry renders the Operations hub; the older screen promise requires Organisations directly, so that full screen contract remains incomplete.

01

EXECUTED GHERKIN STEP

Given a platform administrator opens the exact admin entry **PASS**

 Technical file 

  MDIS system  

Home > Admin

Operations

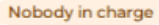
What is waiting on a person at MedQAIR, and where to find anything.

[+ New organisation](#)

Needs a decision

 **[TEST] Release Cleanup Service · nobody in charge**

No active administrator — nobody there can invite anyone.

 [Open](#)

Find

One box for all four registers. A result says which register it came from.

Registers

	Organisations · 9 9 active · 0 deactivated · 1 without an administrator	Open
	Users · 19 17 signed in · 2 invited and never signed in · 0 deactivated	Open
	Economic operators · 8 5 manufacturers · 1 authorised representative · 1 distributor · 1 importer	

Capture SHA-256: 29cb35175d12c00d091d3ab278d963f44e6e733cf55a837e36ac90b898a81427

02

EXECUTED GHERKIN STEP

Then the exact admin entry renders Operations from persisted registers PASS*No visible change at this step; asserted through the API read*

 **Technical file** 

  **MDIS system**  

Home > Admin

Operations

What is waiting on a person at MedQAIR, and where to find anything.

[+ New organisation](#)

Needs a decision

 **[TEST] Release Cleanup Service · nobody in charge**

No active administrator — nobody there can invite anyone.

Nobody in charge [Open](#)

Find

One box for all four registers. A result says which register it came from.

Registers

 **Organisations · 9**

9 active · 0 deactivated · 1 without an administrator

[Open](#)

 **Users · 19**

17 signed in · 2 invited and never signed in · 0 deactivated

[Open](#)

 **Economic operators · 8**

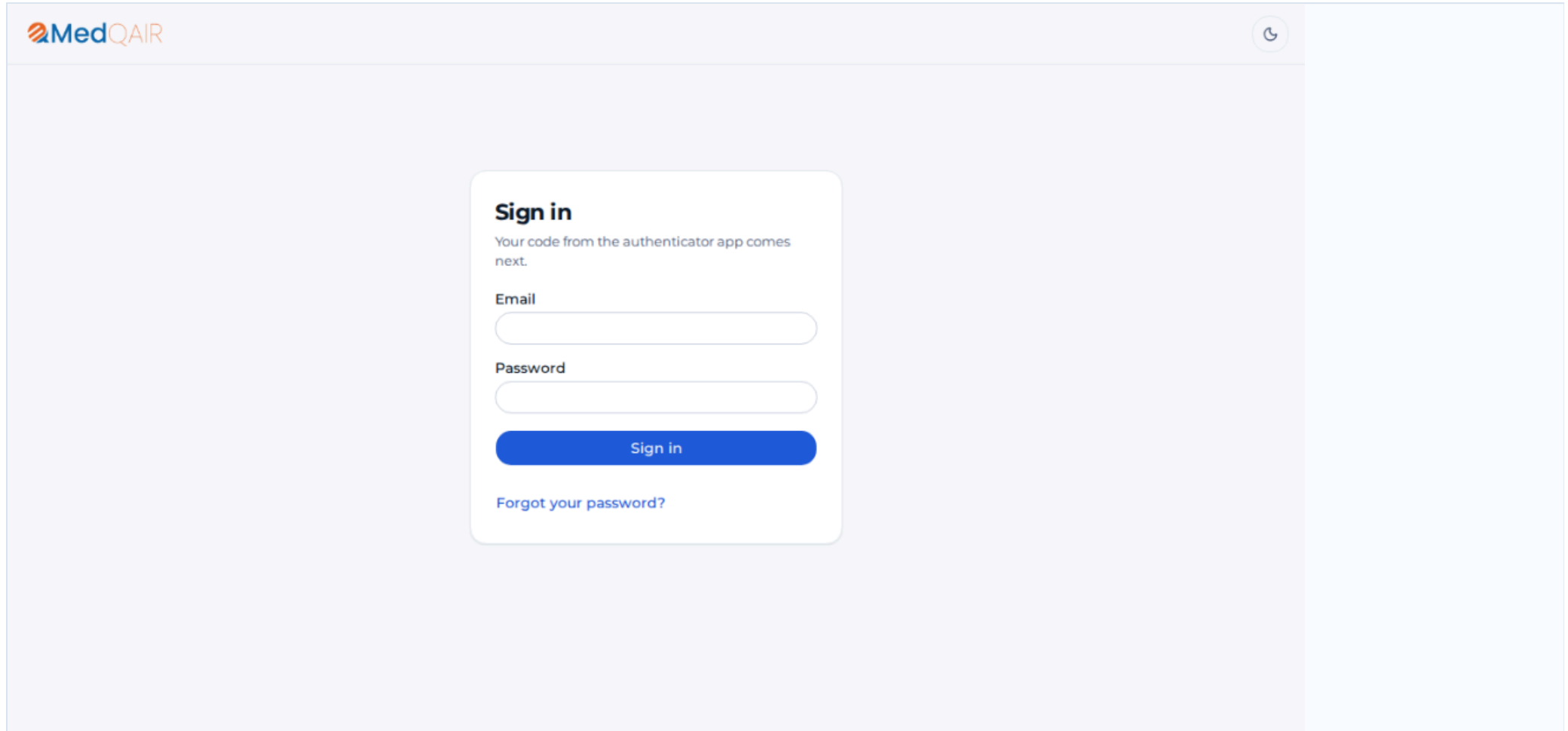
5 manufacturers · 1 authorised representative · 1 distributor · 1 importer

Capture SHA-256: 29cb35175d12c00d091d3ab278d963f44e6e733cf55a837e36ac90b898a81427

03

EXECUTED GHERKIN STEP

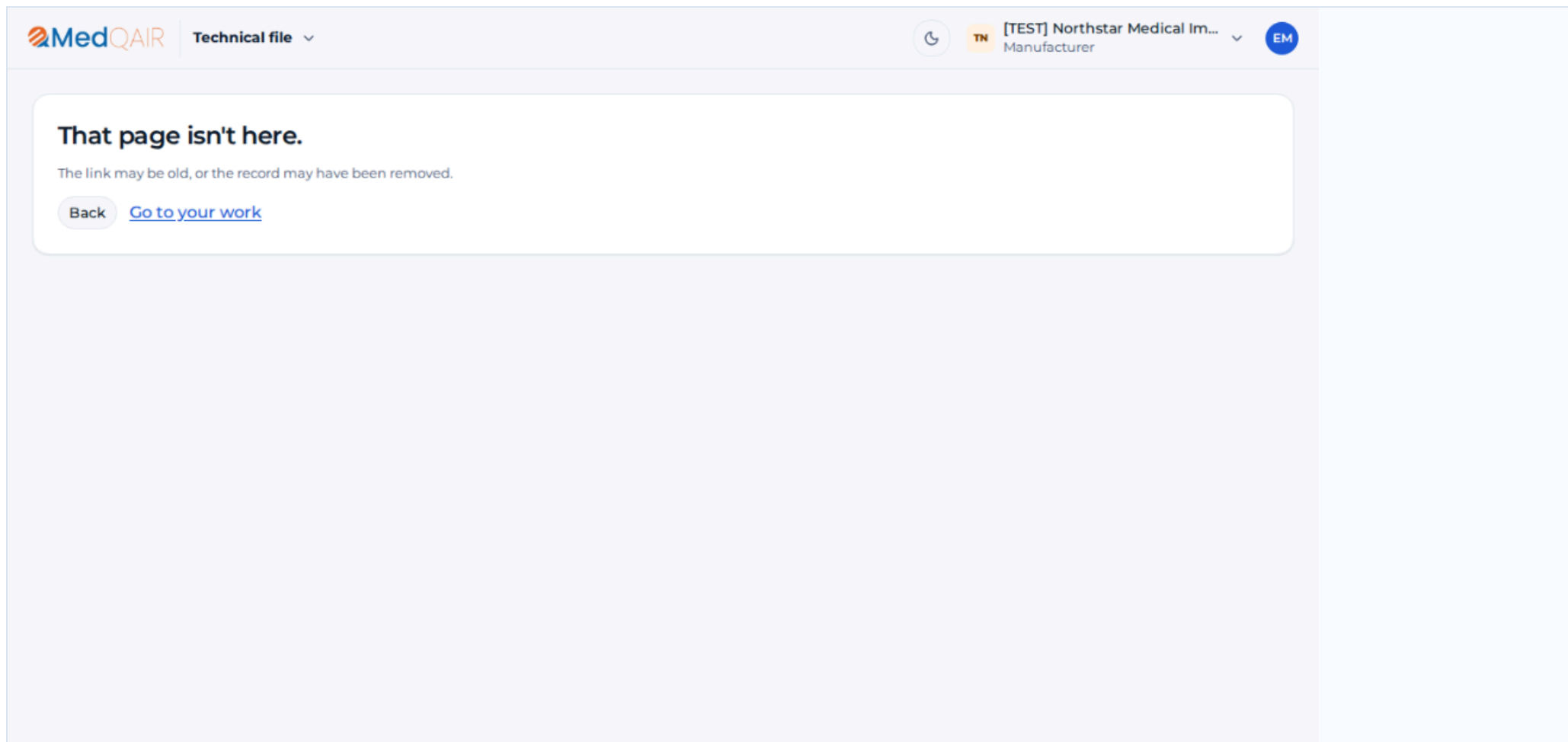
When the platform administrator signs out of this entry **PASS**

The image shows a web application interface for MedQAIR. At the top left is the MedQAIR logo, consisting of a stylized orange and blue 'M' followed by the text 'MedQAIR'. At the top right is a circular icon with a right-pointing arrow. The main content area is a light gray rectangle. In the center of this area is a white rounded rectangle containing a sign-in form. The form has the title 'Sign in' in bold. Below the title is the text 'Your code from the authenticator app comes next.' followed by two input fields: 'Email' and 'Password'. Below these fields is a blue button with the text 'Sign in'. At the bottom of the form is a link that says 'Forgot your password?' in blue text.

Capture SHA-256: 953d9a1220a1b501a0ede3a87b7d5516c6552f0e0d727f3b59246c01ef255e3b

04

EXECUTED GHERKIN STEP

And an actor-scoped caller opens the exact admin entry PASS

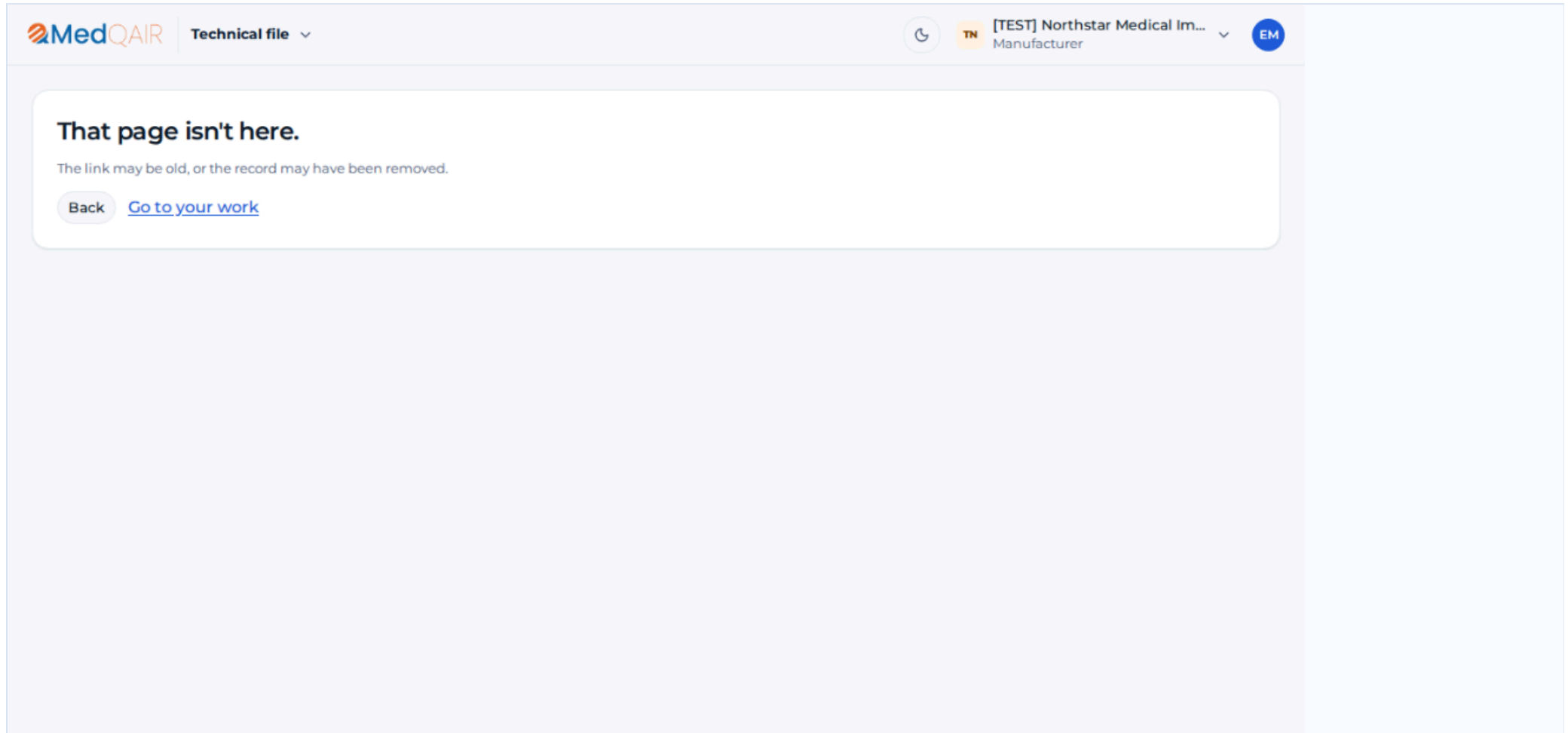
Capture SHA-256: 99d5d062d612eedfbc804191bd341f2b259a44461f1d7761925543ae020a4b67

05

EXECUTED GHERKIN STEP

Then the actor-scoped caller sees the ordinary not-found surface **PASS**

No visible change at this step; the actor-scoped caller remains on the ordinary not-found surface

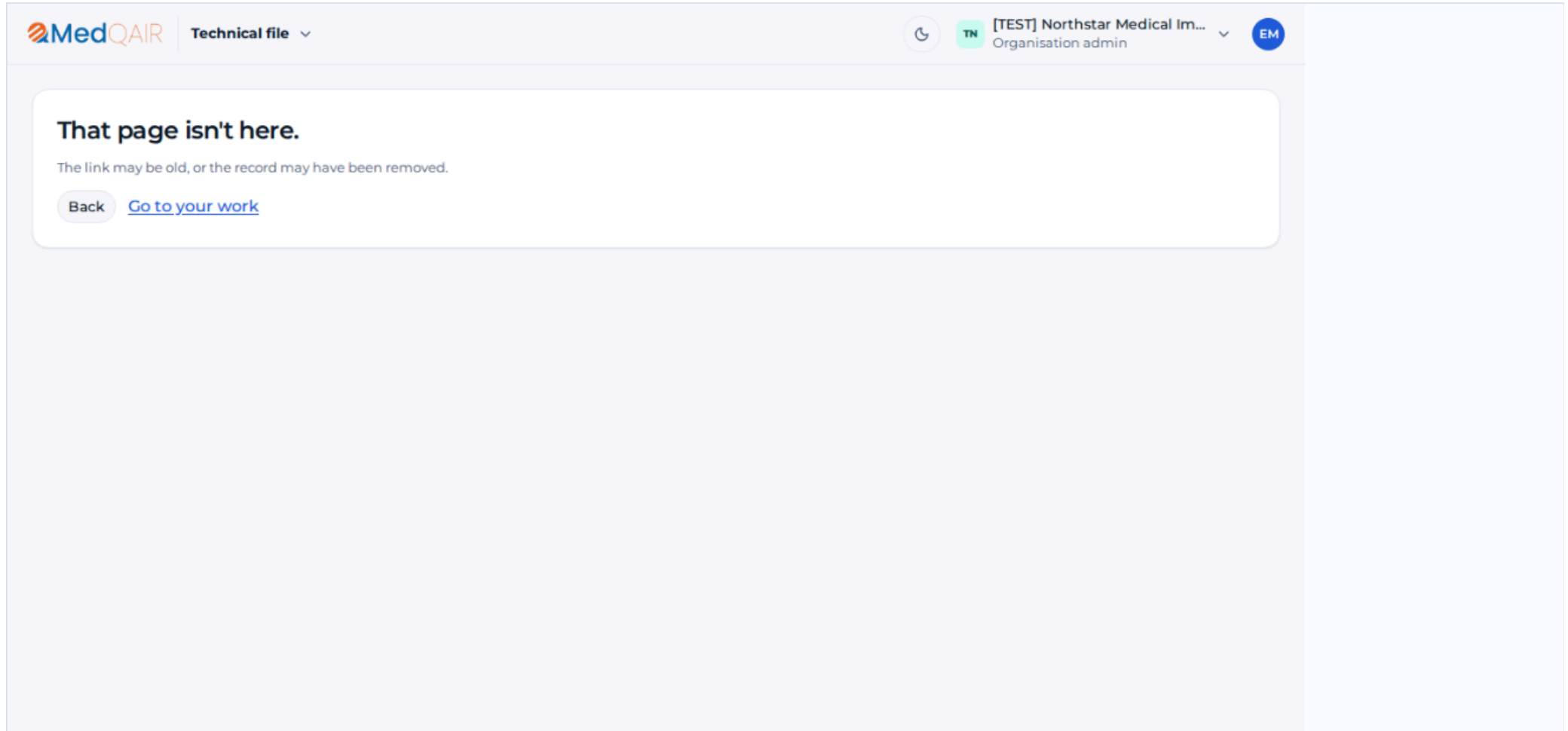


Capture SHA-256: 99d5d062d612eedfbc804191bd341f2b259a44461f1d7761925543ae020a4b67

06

EXECUTED GHERKIN STEP

When the actor-scoped caller selects its organisation context and retries the exact admin entry PASS



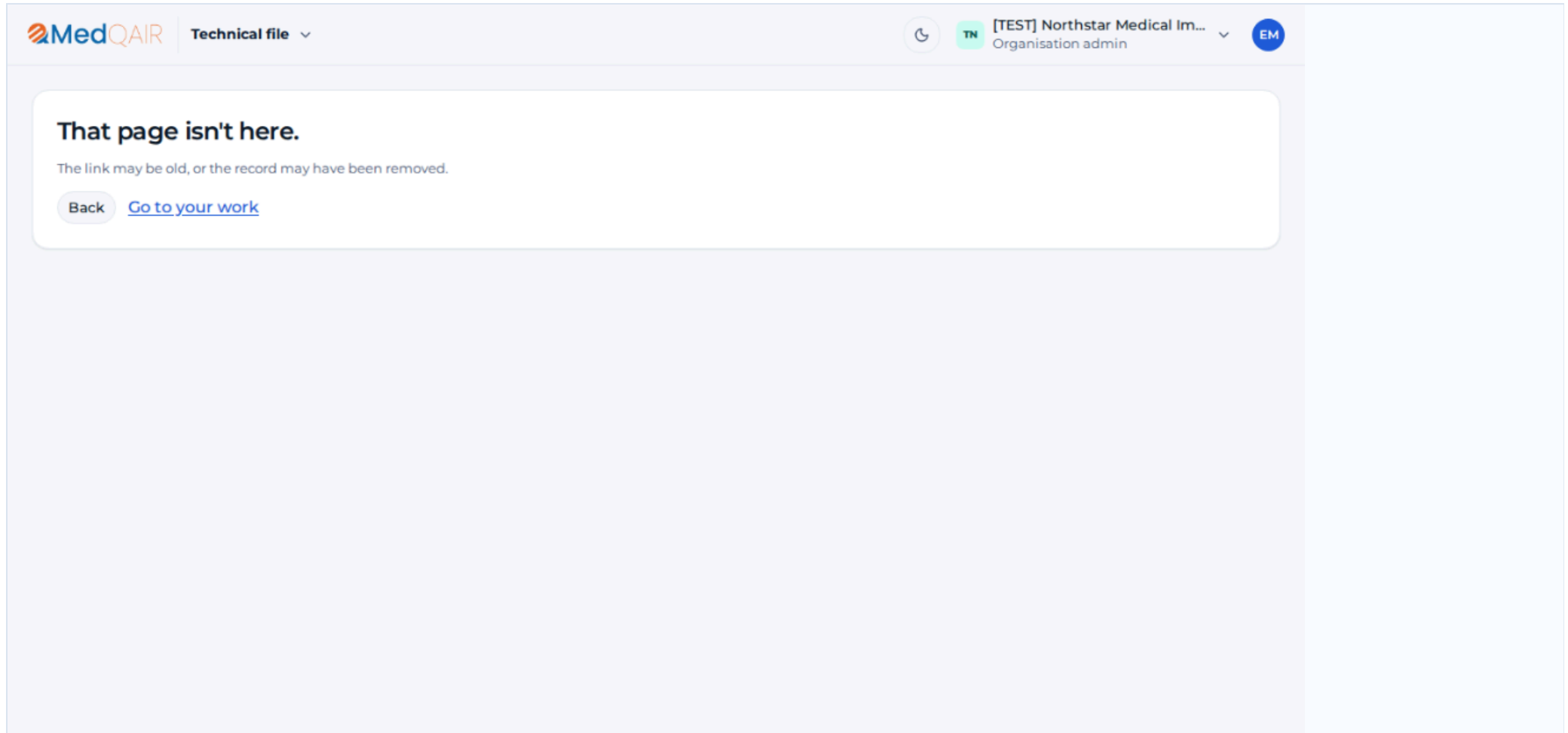
Capture SHA-256: 16b845093113410e8e0552cd190ceae13b4c533abf203de7b96fb8bab0c89983

07

EXECUTED GHERKIN STEP

Then the organisation-scoped caller sees the ordinary not-found surface **PASS**

No visible change at this step; the organisation-scoped caller remains on the ordinary not-found surface

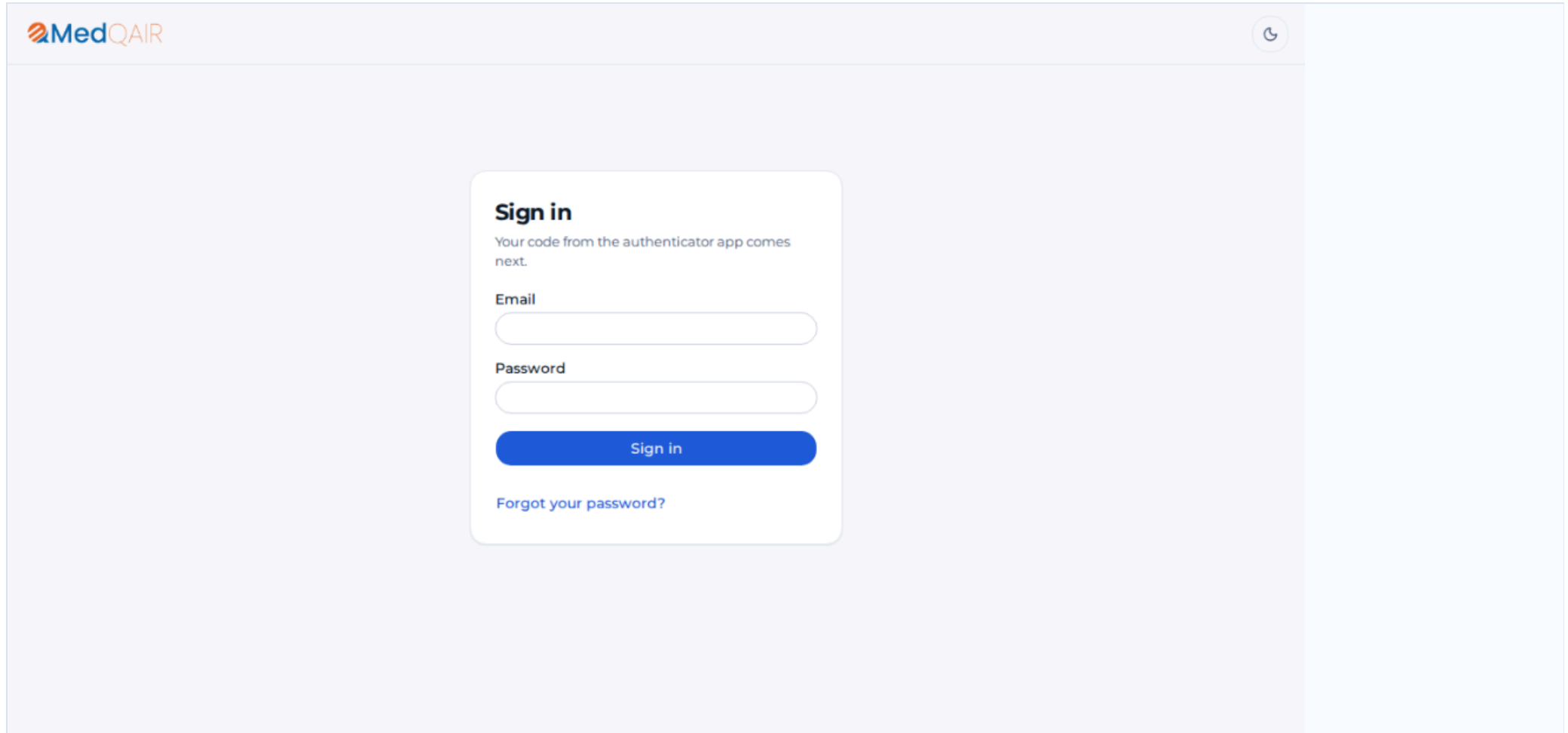


Capture SHA-256: 16b845093113410e8e0552cd190ceae13b4c533abf203de7b96fb8bab0c89983

08

EXECUTED GHERKIN STEP

When the actor-scoped caller signs out **PASS**



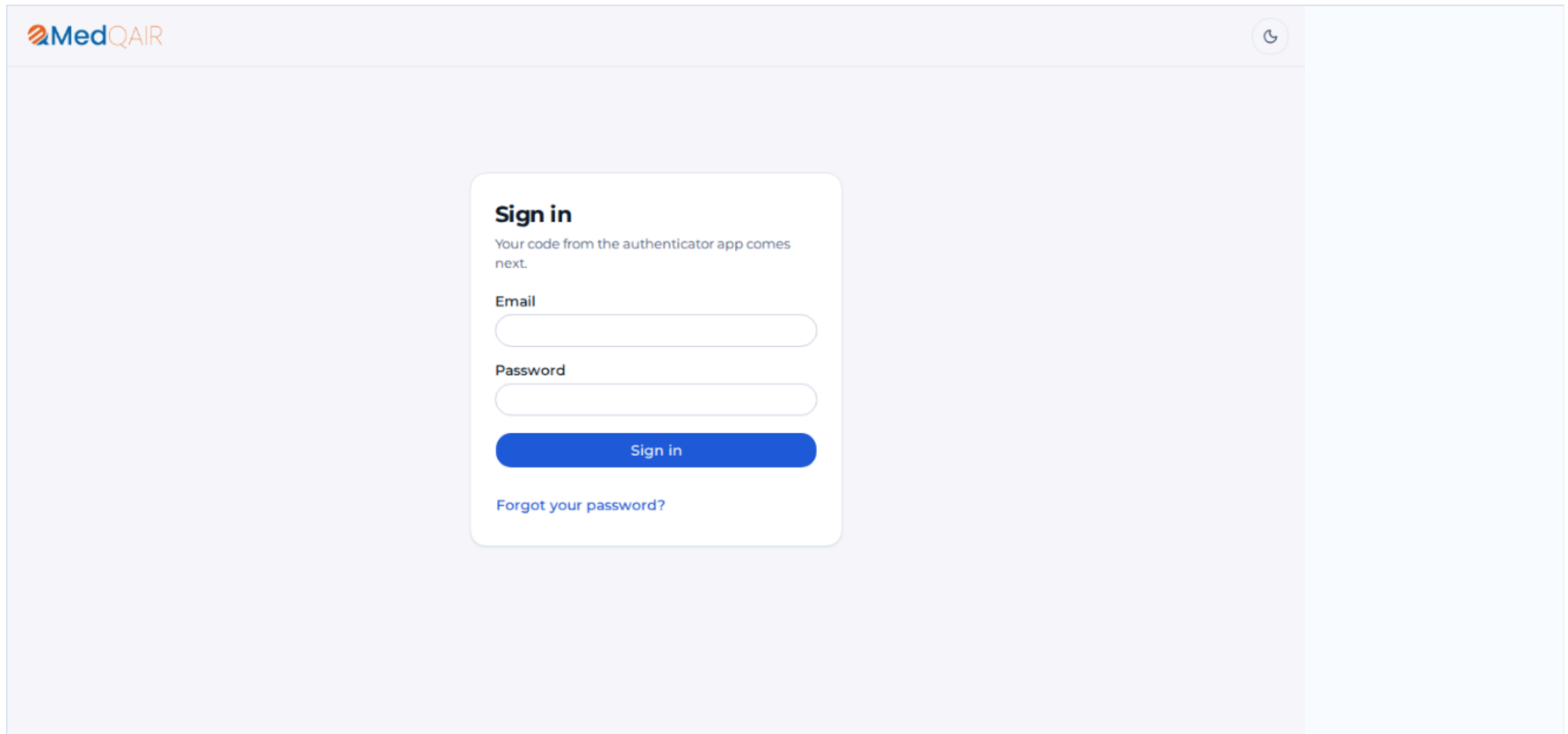
Capture SHA-256: 953d9a1220a1b501a0ede3a87b7d5516c6552f0e0d727f3b59246c01ef255e3b

09

EXECUTED GHERKIN STEP

And a signed-out caller opens the exact admin entry **PASS**

No visible change at this step; opening the protected entry returns the signed-out caller to sign in



The image shows a web application interface for MedQAIR. In the top left corner, the MedQAIR logo is displayed. In the top right corner, there is a circular icon containing a right-pointing arrow. The main content area is a light gray rectangle. Centered within this area is a white rounded rectangle containing the sign-in form. The form has the title "Sign in" in bold. Below the title is a message: "Your code from the authenticator app comes next." There are two input fields: "Email" and "Password", each with a light gray border and rounded corners. Below the "Password" field is a blue button with the text "Sign in" in white. At the bottom of the form is a link that says "Forgot your password?" in blue text.

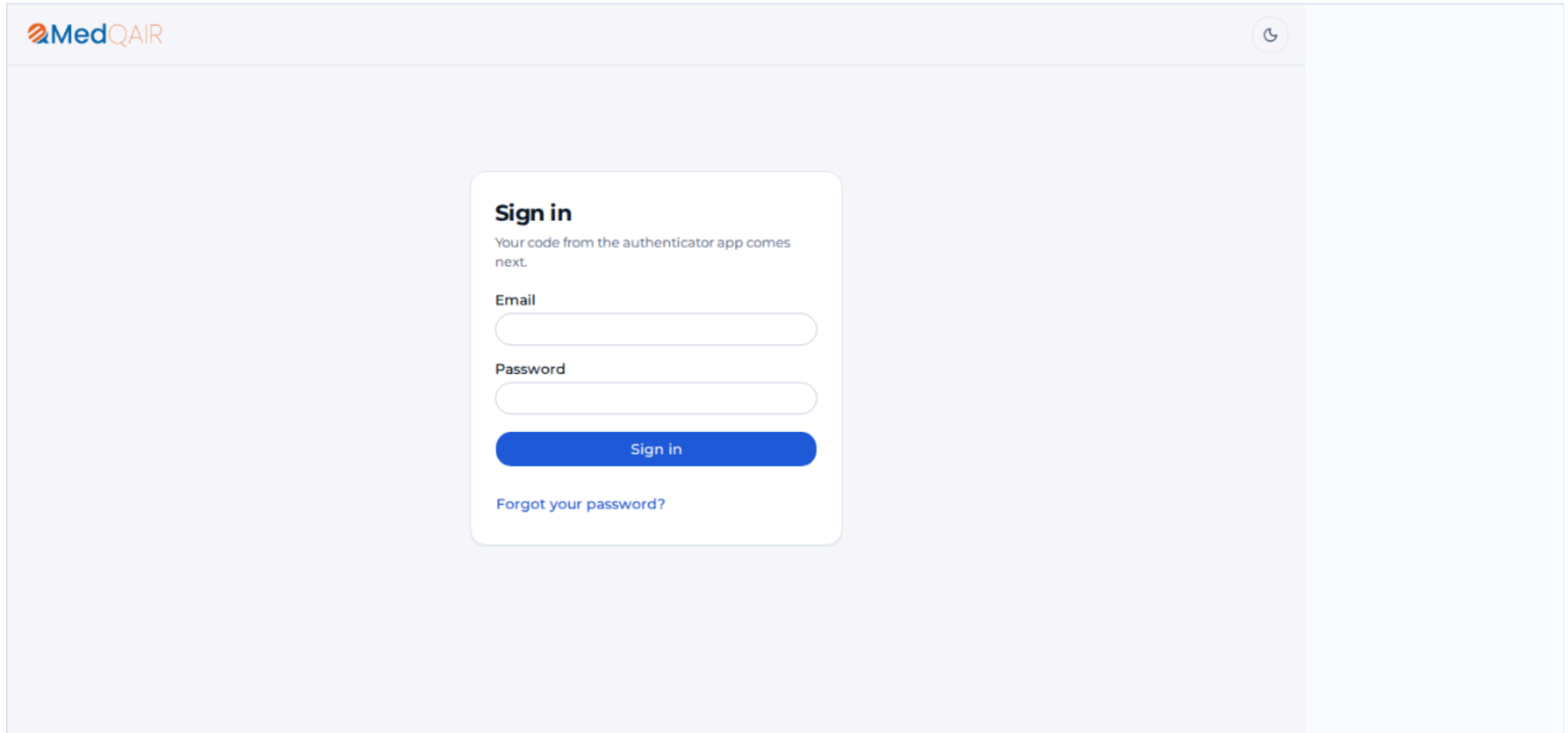
Capture SHA-256: 953d9a1220a1b501a0ede3a87b7d5516c6552f0e0d727f3b59246c01ef255e3b

10

EXECUTED GHERKIN STEP

Then the signed-out caller is redirected to sign in **PASS**

No visible change at this step; the unauthenticated caller remains on the sign-in surface

The image shows a web application interface for MedQAIR. In the top left corner, there is a logo with an orange stylized 'M' followed by the text 'MedQAIR'. In the top right corner, there is a circular icon containing a right-pointing arrow. The main content area is a light gray rectangle. Centered within this area is a white rounded rectangle representing a sign-in card. The card has the title 'Sign in' in bold black text. Below the title is a subtitle: 'Your code from the authenticator app comes next.' There are two input fields: the first is labeled 'Email' and the second is labeled 'Password'. Both fields are empty and have rounded rectangular borders. Below the password field is a solid blue button with the text 'Sign in' in white. At the bottom of the card is a link that says 'Forgot your password?' in a smaller, blue font.

Capture SHA-256: 953d9a1220a1b501a0ede3a87b7d5516c6552f0e0d727f3b59246c01ef255e3b

every organisation row is the persisted read-only projection

Only statuses returned by this run are exercised. The current UI uses Deactivated rather than the older Deleted label; this does not prove every lifecycle status variant.

01 EXECUTED GHERKIN STEP
Given a platform administrator opens the Organisations register from the current account menu

PASS

 Technical file ▾

  MDIS system ▾ 

Home › Admin › Organisations

+ New organisation

Organisations

Every organisation on the platform.

	[TEST] Northstar Medical Imaging e2e-manufacturer-org@medqair.com · 1 identity · set up 9 Sept	Active	Open
	E2E Foreign Manufacturer Co e2e-foreign-manufacturer-org@medqair.com · 1 identity · set up 9 Sept	Active	Open
	[TEST] Flok Health EU e2e-eu-manufacturer-org@medqair.com · 1 identity · set up 9 Sept	Active	Open
	E2E Authorised Rep Co e2e-auth-rep-org@medqair.com · 1 identity · set up 9 Sept	Active	Open
	[TEST] Sectra Distribution e2e-distributor-org@medqair.com · 1 identity · set up 9 Sept	Active	Open
	[TEST] Auth Cutover MFA Organisation e2e-auth-cutover-mfa-org@mdis.invalid · 1 identity · set up 9 Sept	Active	Open
	[TEST] Release Cleanup Service e2e-release-cleanup-org@medqair.com · 1 identity · set up 9 Sept	Active	Open
	[TEST] Harborline Importers e2e-importer-org@medqair.com · 1 identity · set up 9 Sept	Active	Open

Capture SHA-256: 722a7798f097218e4741726cdbf590d47b8be1441362d41d09173ff581e91c81

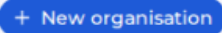
02

EXECUTED GHERKIN STEP

Then every organisation row matches its persisted projection without dead controls PASS*No visible change at this step; every organisation row remains the persisted read-only projection*

 Technical file 

  MDIS system  

Home › Admin › Organisations 

Organisations

Every organisation on the platform.

	[TEST] Northstar Medical Imaging e2e-manufacturer-org@medqair.com · 1 identity · set up 9 Sept	Active	Open
	E2E Foreign Manufacturer Co e2e-foreign-manufacturer-org@medqair.com · 1 identity · set up 9 Sept	Active	Open
	[TEST] Flok Health EU e2e-eu-manufacturer-org@medqair.com · 1 identity · set up 9 Sept	Active	Open
	E2E Authorised Rep Co e2e-auth-rep-org@medqair.com · 1 identity · set up 9 Sept	Active	Open
	[TEST] Sectra Distribution e2e-distributor-org@medqair.com · 1 identity · set up 9 Sept	Active	Open
	[TEST] Auth Cutover MFA Organisation e2e-auth-cutover-mfa-org@mdis.invalid · 1 identity · set up 9 Sept	Active	Open
	[TEST] Release Cleanup Service e2e-release-cleanup-org@medqair.com · 1 identity · set up 9 Sept	Active	Open
	[TEST] Harborline Importers e2e-importer-org@medqair.com · 1 identity · set up 9 Sept	Active	Open

Capture SHA-256: 722a7798f097218e4741726cdbf590d47b8be1441362d41d09173ff581e91c81

Users search preserves exact identity and omits MFA state

01

EXECUTED GHERKIN STEP

Given a platform administrator has a run-owned phone-search user ready PASS



Technical file ▾



MSMDIS system ▾
System

AD

Your work
Wednesday 9 September



0
drafts to finish



0
returned for changes



0
waiting on a partner



38
devices, 13 released

Needs you



Your work queue didn't load.
Your work is safe. Try again, or come back in a minute.

Try again

Devices · 38

All 38 ▸



Name, UDI-DI or Basic UDI-DI

PA

PulseView AR Validation ...

Unreleased

AD

AtlasView Ownership Bo...

Unreleased

AD

AtlasView Distributor Gu...

Unreleased

AD

AtlasView Distributor Veri...

Unreleased

AI

AtlasView Importer Verifi...

Unreleased

AA

AtlasView AR Validation ...

Unreleased

Capture SHA-256: 94a15c838831ad1229d74b4dd1402530d77bad29ceb618ebf76a0fbec749573b

MDIS walkthrough · 309 / 418

02

EXECUTED GHERKIN STEP

When the platform administrator opens the Users register for wave2 search PASS

 Technical file 

  MDIS system  

[Home](#) > [Admin](#) > [Users](#) 

Capture SHA-256: be45e99f10f6c753edcd8befcca91cfc8e54d396aea797a237a4c5892feb9177

03

EXECUTED GHERKIN STEP

When the platform administrator searches by the run-owned user's name **PASS**

The screenshot shows the MedQAIR platform's 'Users' management interface. The top navigation bar includes the MedQAIR logo, a 'Technical file' dropdown, and system status indicators for 'MS' (MDIS system) and 'AD'. The breadcrumb trail indicates the current location: 'Home > Admin > Users'. The main heading is 'Users', with a subtext 'Every user on the platform, across every organisation.' Below this is a search bar with the placeholder 'Search by name, email or phone'. The search input field contains the text 'Wave Search-372a102a', and there are 'Search' and 'Clear' buttons. A single search result is displayed in a card format, showing a purple 'ws' icon, the name 'Wave Search-372a102a', the email 'e2e-wave2-search-372a102a-cb11-4da3-b0b5-c65c6f8c32d5@example.com', the role 'Member', and the organization '[TEST] Northstar ...'. To the right of the user details are two buttons: 'Invited' (orange) and 'Open' (blue).

MedQAIR Technical file MS MDIS system System AD

Home > Admin > Users

Users

Every user on the platform, across every organisation.

Search by name, email or phone

Wave Search-372a102a Search Clear

ws **Wave Search-372a102a**
e2e-wave2-search-372a102a-cb11-4da3-b0b5-c65c6f8c32d5@example.com · Member · [TEST] Northstar ... Invited Open

Capture SHA-256: 58fe2fe7f8f6a35f3b206c227bb9170023977a4da2e673960d31bd04022b55ce

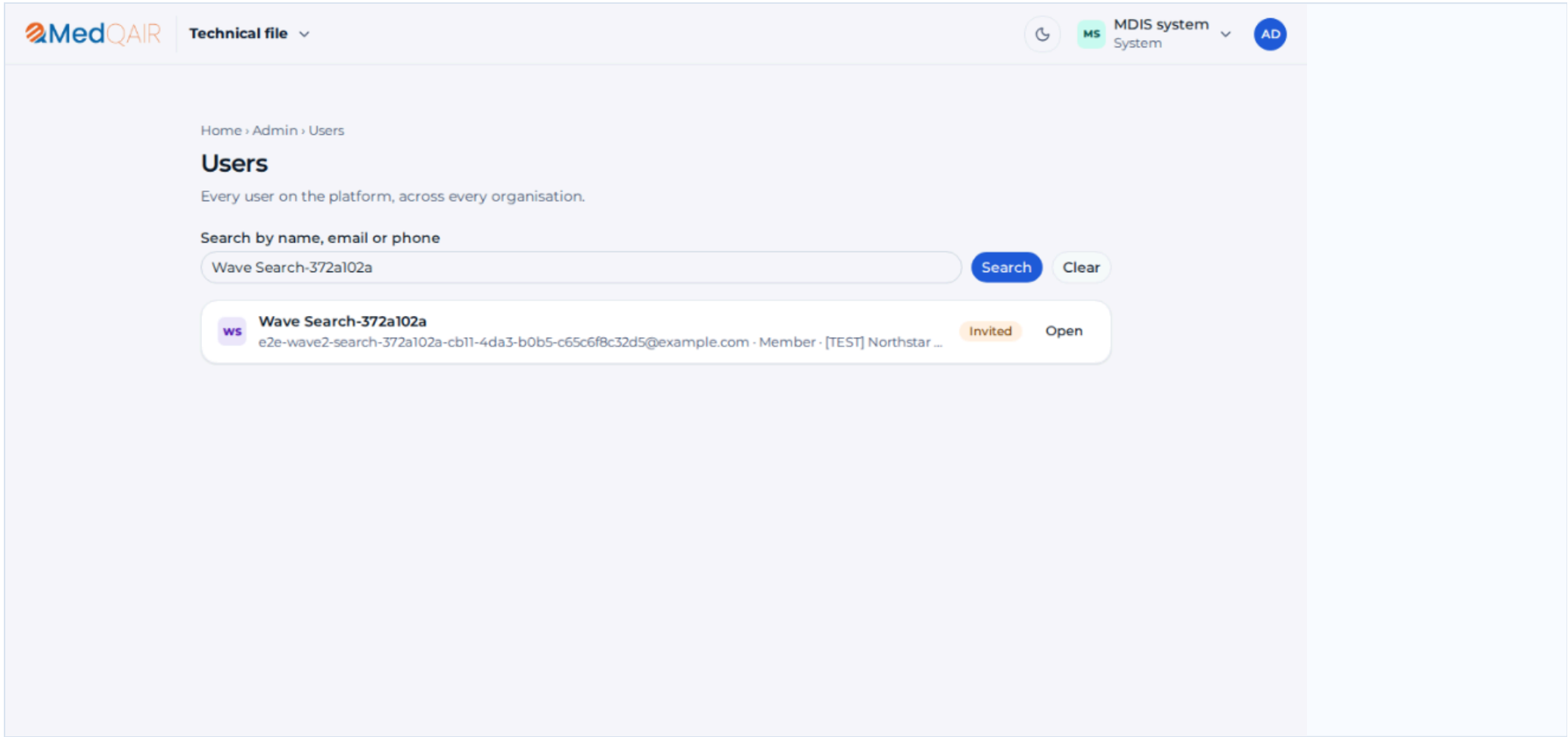
04

EXECUTED GHERKIN STEP

Then the name search shows only the run-owned identity without MFA controls

PASS

No visible change at this step; the exact run-owned identity remains the only name result without an MFA claim



Capture SHA-256: 58fe2fe7f8f6a35f3b206c227bb9170023977a4da2e673960d31bd04022b55ce

05

EXECUTED GHERKIN STEP

When the platform administrator searches by the run-owned user's email PASS

The screenshot displays the MedQAIR 'Users' management interface. At the top, the MedQAIR logo is on the left, and navigation links for 'Technical file', 'MDIS system', and 'AD' are on the right. The breadcrumb trail indicates the path: Home > Admin > Users. The main heading is 'Users', followed by the description 'Every user on the platform, across every organisation.' Below this is a search bar with the placeholder text 'Search by name, email or phone'. The search bar contains the email address 'e2e-wave2-search-372a102a-cb11-4da3-b0b5-c65c6f8c32d5@example.com'. To the right of the search bar are 'Search' and 'Clear' buttons. Below the search bar, a single user is listed in a card. The card has a purple 'ws' icon, the name 'Wave Search-372a102a', and the email address 'e2e-wave2-search-372a102a-cb11-4da3-b0b5-c65c6f8c32d5@example.com'. To the right of the email, it says 'Member · [TEST] Northstar ...'. Further right are two buttons: 'Invited' (orange) and 'Open' (blue).

Home > Admin > Users

Users

Every user on the platform, across every organisation.

Search by name, email or phone

e2e-wave2-search-372a102a-cb11-4da3-b0b5-c65c6f8c32d5@example.com

Search Clear

ws **Wave Search-372a102a**
e2e-wave2-search-372a102a-cb11-4da3-b0b5-c65c6f8c32d5@example.com · Member · [TEST] Northstar ...

Invited Open

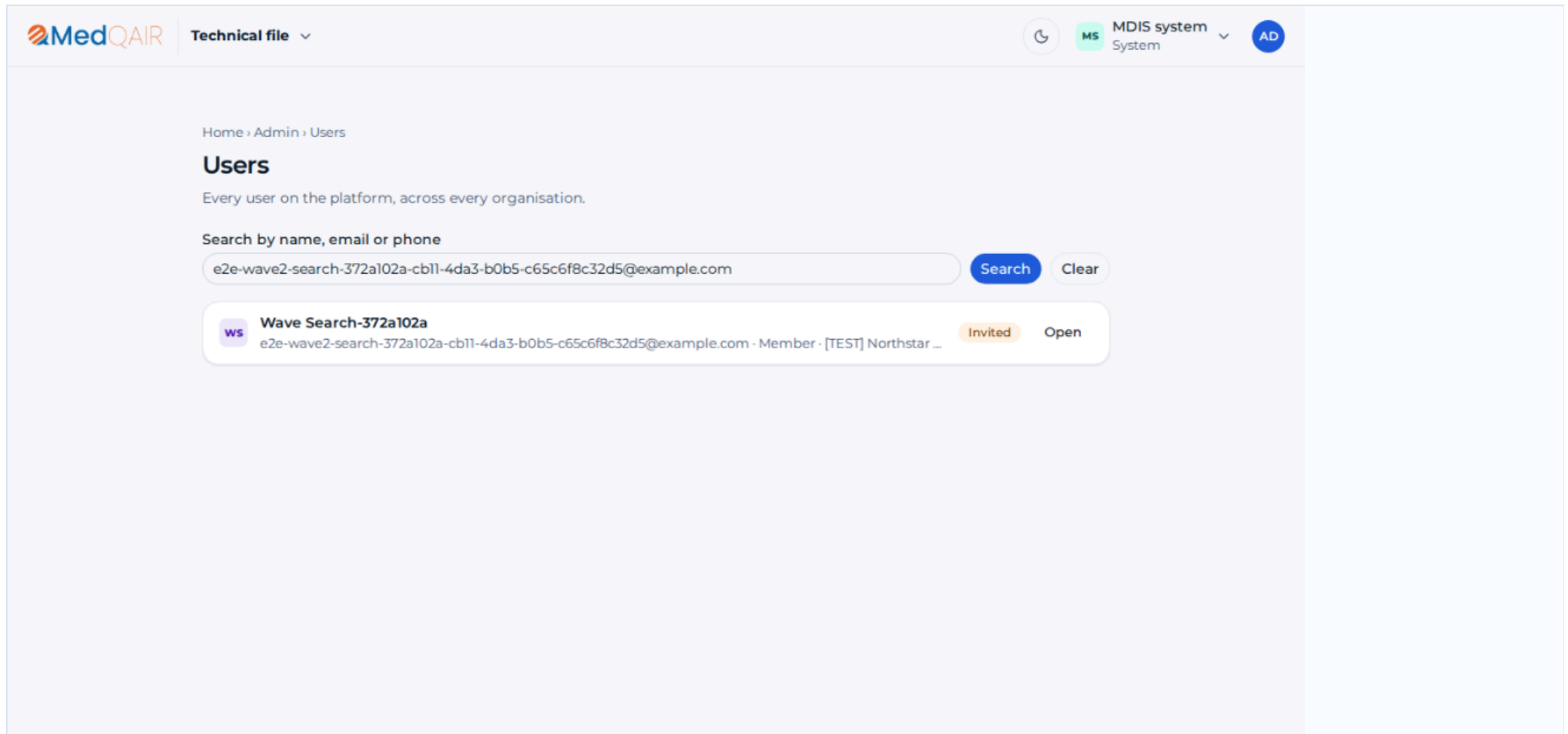
Capture SHA-256: 7cb5a8bff03bddfc7f4e22bc9efdd772520c1c6db9ac4e7c7e9b4cfa53b12b20

06

EXECUTED GHERKIN STEP

Then the email search shows only the run-owned identity without MFA controls **PASS**

No visible change at this step; the exact run-owned identity remains the only email result without an MFA claim



MedQAIR Technical file

Home › Admin › Users

Users

Every user on the platform, across every organisation.

Search by name, email or phone

e2e-wave2-search-372a102a-cb11-4da3-b0b5-c65c6f8c32d5@example.com Search Clear

ws	Wave Search-372a102a	e2e-wave2-search-372a102a-cb11-4da3-b0b5-c65c6f8c32d5@example.com · Member · [TEST] Northstar ...	Invited	Open
----	----------------------	---	---------	------

Capture SHA-256: 7cb5a8bff03bddfc7f4e22bc9efdd772520c1c6db9ac4e7c7e9b4cfa53b12b20

07

EXECUTED GHERKIN STEP

When the platform administrator searches by the run-owned user's phone **PASS**

The screenshot shows the MedQAIR platform's 'Users' management interface. The top navigation bar includes the MedQAIR logo, a 'Technical file' dropdown, and system status indicators for 'MS' and 'MDIS system System'. The breadcrumb trail indicates the current location: 'Home > Admin > Users'. The main heading is 'Users', with a subtext 'Every user on the platform, across every organisation.' Below this is a search bar with the placeholder 'Search by name, email or phone'. The search input field contains the phone number '6003720102', and there are 'Search' and 'Clear' buttons. A single search result is displayed in a card format, showing a user icon with 'ws', the name 'Wave Search-372a102a', and the email 'e2e-wave2-search-372a102a-cb11-4da3-b0b5-c65c6f8c32d5@example.com'. The user is identified as a 'Member' and '[TEST] Northstar ...'. To the right of the user details are two buttons: 'Invited' (highlighted in orange) and 'Open'.

Home > Admin > Users

Users

Every user on the platform, across every organisation.

Search by name, email or phone

6003720102 **Search** Clear

ws **Wave Search-372a102a**
e2e-wave2-search-372a102a-cb11-4da3-b0b5-c65c6f8c32d5@example.com · Member · [TEST] Northstar ... **Invited** **Open**

Capture SHA-256: ee07dccc6cdce240b3f64985eb8e7fa44a72fe4506ec8122d8aa23a66ba90b4b

08

EXECUTED GHERKIN STEP

Then the phone search shows only the run-owned identity without MFA controls PASS

No visible change at this step; the exact run-owned identity remains the only phone result without an MFA claim

 **Technical file** 

  **MDIS system**  

[Home](#) > [Admin](#) > [Users](#)

Users

Every user on the platform, across every organisation.

Search by name, email or phone

Search **Clear**



Wave Search-372a102a
e2e-wave2-search-372a102a-cb11-4da3-b0b5-c65c6f8c32d5@example.com · Member · [TEST] Northstar ...

Invited **Open**

Capture SHA-256: ee07dccc6cdce240b3f64985eb8e7fa44a72fe4506ec8122d8aa23a66ba90b4b

09

EXECUTED GHERKIN STEP

When the platform administrator clears the Users search PASS

 Technical file 

  MDIS system  System 

[Home](#) > [Admin](#) > [Users](#)

Search

Capture SHA-256: be45e99f10f6c753edcd8befcca91cfc8e54d396aea797a237a4c5892feb9177

10

EXECUTED GHERKIN STEP

Then the empty Users search lists every persisted row without MFA state

PASS

No visible change at this step; the empty search remains the complete persisted Users projection without MFA state

MedQAIR

Technical file

MS

MDIS system

System

AD

Home > Admin > Users

Users

Every user on the platform, across every organisation.

Search by name, email or phone

e.g. ada@northstar.com

Search

MA	Medqair Admin admin@medqair.com · Platform admin	Active	Open
EM	E2E Manufacturer e2e-manufacturer@medqair.com · Member · [TEST] Northstar Medical Imaging	Active	Open
EF	E2E Foreign Manufacturer e2e-foreign-manufacturer@medqair.com · Member · E2E Foreign Manufacturer Co	Active	Open
EE	E2E EU Manufacturer e2e-eu-manufacturer@medqair.com · Member · [TEST] Flok Health EU	Active	Open
EA	E2E AuthRep e2e-auth-rep@medqair.com · Member · E2E Authorised Rep Co	Active	Open
ED	E2E Distributor e2e-distributor@medqair.com · Member · [TEST] Sectra Distribution	Active	Open
EA	E2E Auth Cutover MFA e2e-auth-cutover-mfa@mdis.invalid · Member · [TEST] Auth Cutover MFA Organisation	Active	Open

Capture SHA-256: be45e99f10f6c753edcd8befcca91cfc8e54d396aea797a237a4c5892feb9177

features/registration-vigilance/registration-wave2.feature · @SR-039 @MODULE:EUDAMED-REGISTRATION @UR-003 @REGISTRATION-WAVE2 @PERSISTENT-ENTRY-POINTS-V5-ROUND-8.1 @REGISTRATION-EUDAMED.3

PASS

A new device's registration door returns to the device before its first change

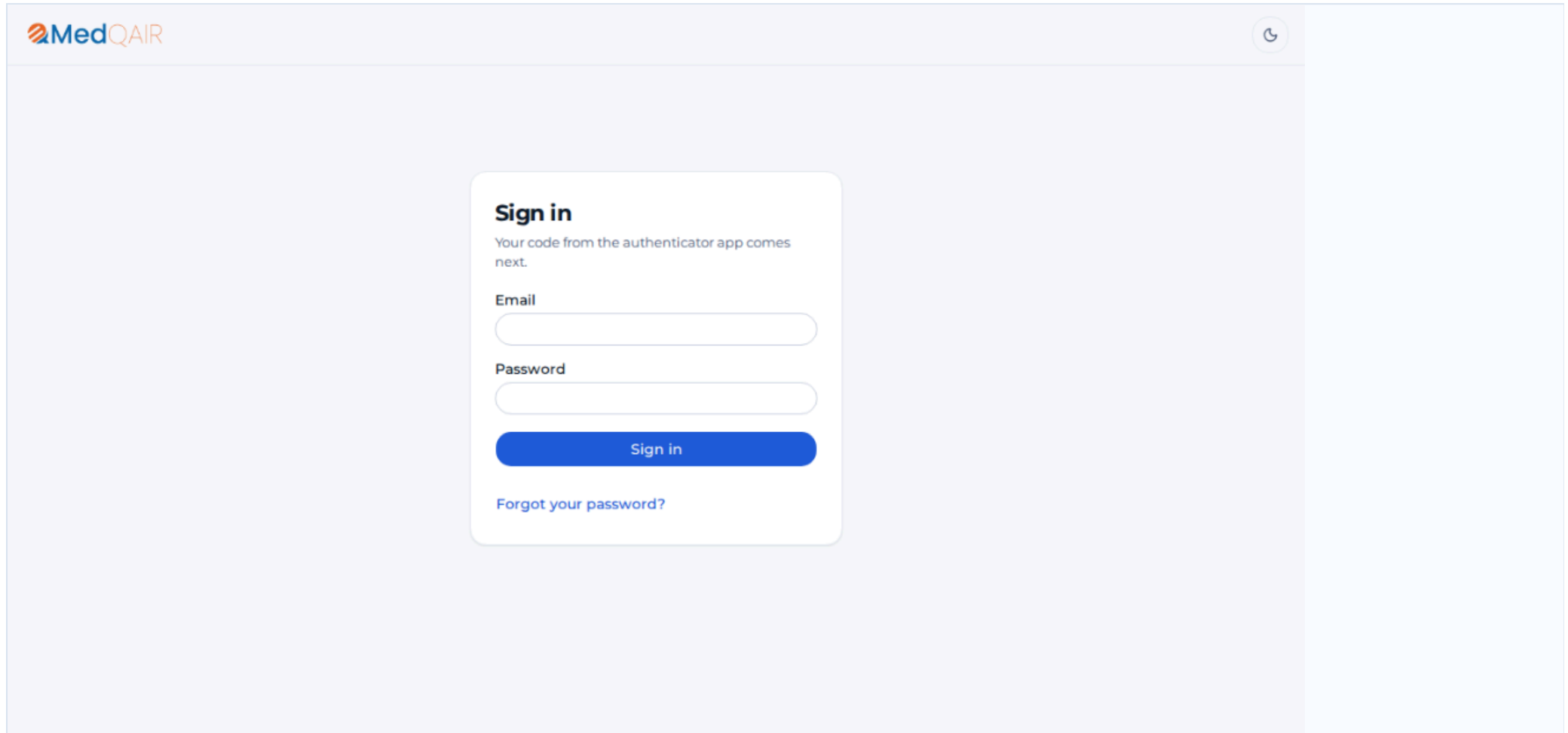
Device creation retains an internal identity placeholder. This journey proves that opening registration does not activate an authority registration or silently create a release; a registration-only

draft is not implemented by this entry.

01

EXECUTED GHERKIN STEP

Given the redesign sign-in page **PASS**



Sign in

Your code from the authenticator app comes next.

Email

Password

Sign in

[Forgot your password?](#)

Capture SHA-256: 953d9a1220a1b501a0ede3a87b7d5516c6552f0e0d727f3b59246c01ef255e3b

02

EXECUTED GHERKIN STEP

When I sign in to the redesign as the EU manufacturer PASS

 Technical file 

   [TEST] Flok Health EU Manufacturer  

Your work

[TEST] Flok Health EU - Wednesday 9 September

 **5**
drafts to finish

 **0**
returned for changes

 **0**
waiting on a partner

 **15**
devices, 12 released

+ Add a device

Needs you

5 drafts

 **VitaPulse Monitor**
E2E portfolio VitaPulse Monitor registration draft · 2.0

Continue

 **Flok Posture Coach**
1.0 first release

Continue

 **E2E Journey Device 1788933721006342**
Change 2

Continue

 **E2E Journey Device 1788933770899946**
2 open drafts · Change 3

Continue

Devices · 15

All 15 >

 **Flok Health**

Unreleased

 **Demo Registered Device**
2.0.0 released 9 Sept

Released

 **AeroVent Home**
1.0 released 9 Sept

Released

 **OrthoFix Pro**
1.0 released 9 Sept

Released

 **VitaPulse Monitor**
1.0 released 9 Sept · E2E portfoli...

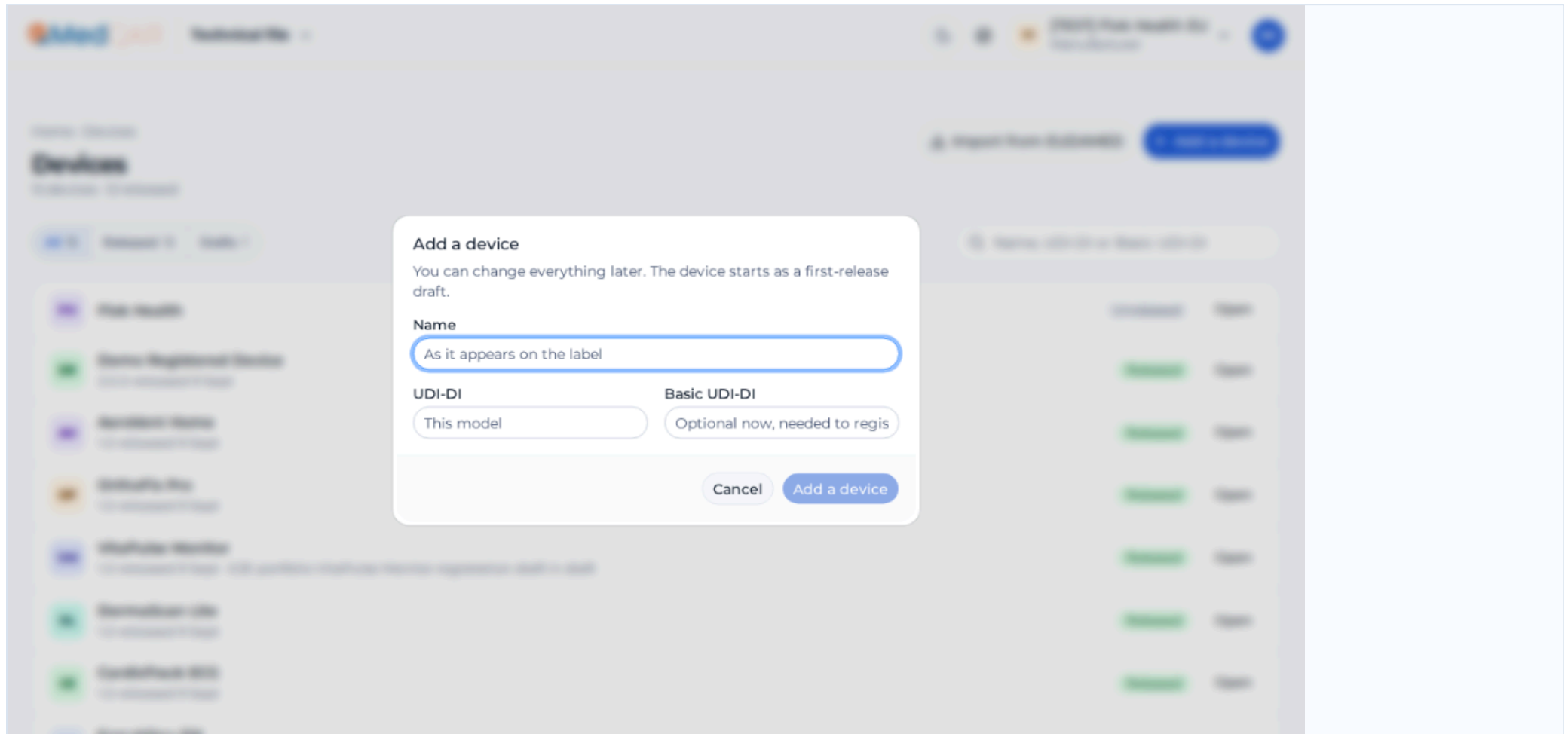
Released

 **DemoSaaS Lite**

Capture SHA-256: 89a10d6630e4ab749913bb5f24ad572bb6ed322b9b54ea7b6f682aef43bb63cf

03

EXECUTED GHERKIN STEP

And I open the redesign's add-device form **PASS**

Capture SHA-256: be389250f6fc560eebcb52fca70ec16903e391fe82e4ae76bbc9dcff6b7122fa

04

EXECUTED GHERKIN STEP

And I submit a device with a unique name and UDI-DI PASS

 Technical file 

   [TEST] Flok Health EU
Manufacturer  

Home > Devices > E2E Journey Device 1788933792070184

 **E2E Journey Device 1788933792070184** Unreleased
not released yet · Basic UDI-DI —

Choose who 

Changes and releases

No changes yet.

Registration Open

Not started. EUDAMED needs every answer.

Who can open it Choose who

Only you, so far.

Identification

UDI-DI
E2E-1788933792070184

Basic UDI-DI
—

UDI-PI
—

Capture SHA-256: 6fd16825e715ea8c64277115c35b9b58cd21f31f5fe0593676e79c7960d90769

05

EXECUTED GHERKIN STEP

And I open the wave-two device's Registration fact without a change **PASS**

The screenshot displays the MedQAIR Technical file interface. The top navigation bar includes the MedQAIR logo, a 'Technical file' dropdown, and user information: '[TEST] Flok Health EU Manufacturer' with a dropdown arrow and a blue 'EE' button. The main content area shows a breadcrumb trail: 'Home > E2E Journey Device 1788933792070184 > Registration'. Below this is a blue box with a document icon and the title 'Registration', followed by the subtitle 'E2E Journey Device 1788933792070184 · EUDAMED device registration · not started'. A yellow callout box contains the message: 'Start a change from the device before adding a regulatory registration.'

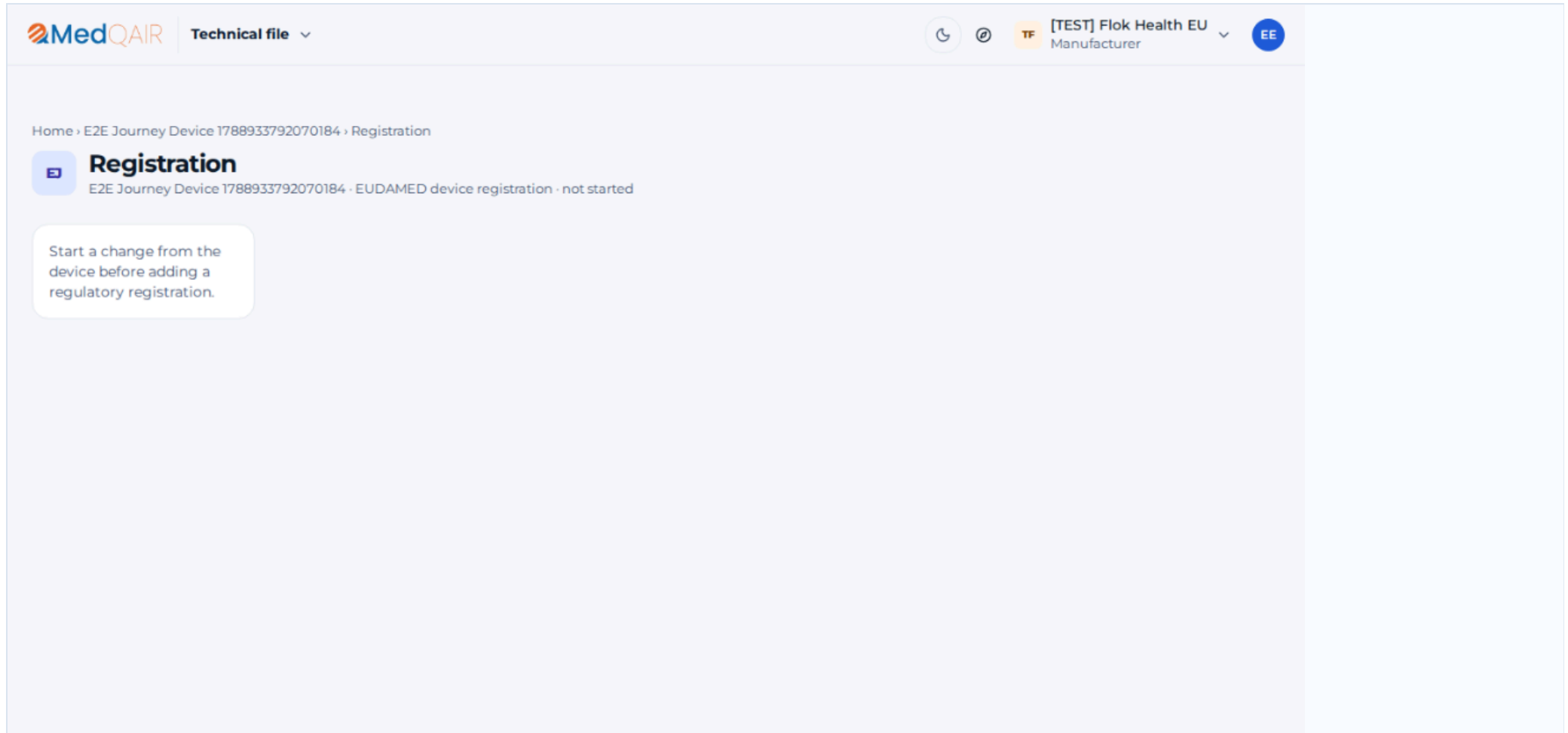
Capture SHA-256: bc9ff5e50448e46c23829e4cafb1771809b67cc0c11ff65c59bd158fd7a8f1b8

06

EXECUTED GHERKIN STEP

Then the wave-two registration entry preserves its placeholder without opening a change **PASS**

No visible change at this step; asserted through the API read



Capture SHA-256: bc9ff5e50448e46c23829e4cafb1771809b67cc0c11ff65c59bd158fd7a8f1b8

07

EXECUTED GHERKIN STEP

When I return through the registration breadcrumb and start the first wave-two change

PASS

MedQAIR Technical file [TEST] Flok Health EU Manufacturer EE

Home > E2E Journey Device 1788933792070184 > Change 1

Change 1 Draft

Version 1.0 wave-two entry Rename

Documents 0 Find Add files

Drop PDFs here · section guessed from the filename, you confirm

No documents yet.

Ready to release? Ready

- ✓ Every upload has a section.
Settings / Review policy · Documents
- ⚠ This device's target market is not recorded — add its EUDAMED registration from the device's Registration page; the registration records the market.
Who receives it · Release authority & reviewers · recommended — you can still release
MDIS compares your organisation's country (from its SRN) with this device's market. Your representative is appointed under Who receives it — a partner you are already connected to at once, a new one once they accept the invitation. Confirming records that the appointment covers this market.
[Open Who receives it](#)

Capture SHA-256: 6dfa3603d8abd9f81c5a0b724c7bfc148efc1a27a800458ac845b794a539c03

08

EXECUTED GHERKIN STEP

And I open the wave-two change's persistent registration link **PASS**

 Technical file 

 [TEST] Flok Health EU
Manufacturer  

Home › E2E Journey Device 1788933792070184 › Registration

 **Registration**
E2E Journey Device 1788933792070184 · EUDAMED device registration · not started

EUROPEAN UNION ·
EUDAMED

**Add device
registration**
Confirm the authority
facts that identify this
device. The questionnaire
opens next and remains
attached to this change.

Applicable
legislation

MDR 

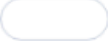
Device
class

Class 

Commercial
name

E2E Jour

Basic UDI-
DI



Basic UDI-
DI issuing
agency

UDI-DI
issuing
agency

Capture SHA-256: 0328fdc469883a82b2a07323279a47e5f62344402ed68863401ab19e86d7beb3

09

EXECUTED GHERKIN STEP

Then the first wave-two registration setup belongs to that exact device and change

PASS

No visible change at this step; asserted through the API read

 **Technical file** 

   **[TEST] Flok Health EU** 
Manufacturer 

Home › E2E Journey Device 1788933792070184 › Registration



Registration
E2E Journey Device 1788933792070184 · EUDAMED device registration · not started

EUROPEAN UNION · EUDAMED

Add device registration
Confirm the authority facts that identify this device. The questionnaire opens next and remains attached to this change.

Applicable legislation

MDR 

Device class

Class 

Commercial name

E2E Jour

Basic UDI-DI

Basic UDI-DI issuing agency

UDI-DI issuing agency

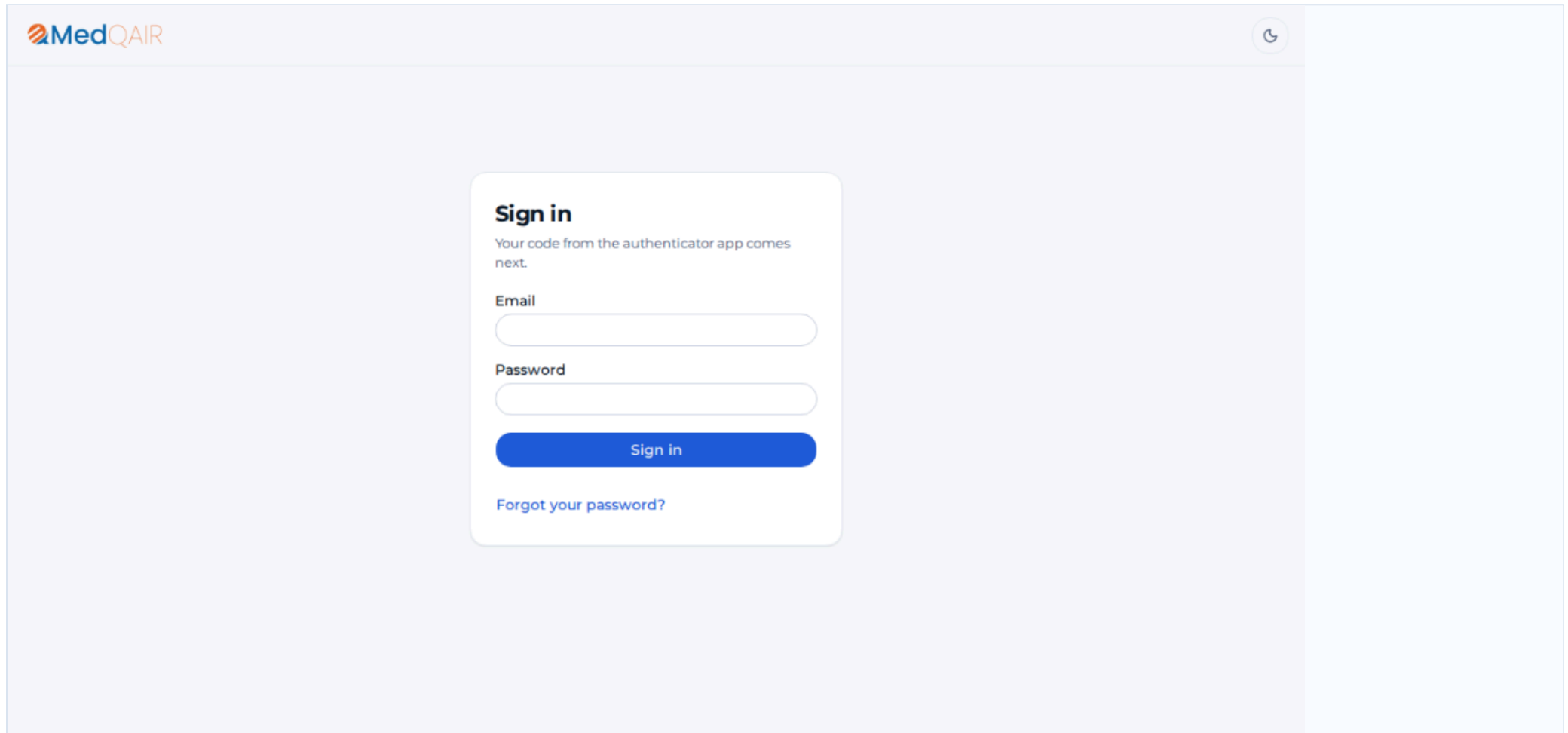
Capture SHA-256: 0328fdc469883a82b2a07323279a47e5f62344402ed68863401ab19e86d7beb3

The current MDR catalogue retains every question and opens its own guidance

This run exercises six topics containing 65 MDR questions. The older 35-question and IVDR presentation promises are not established by this journey.

01

EXECUTED GHERKIN STEP

Given the redesign sign-in page **PASS**

Capture SHA-256: 953d9a1220a1b501a0ede3a87b7d5516c6552f0e0d727f3b59246c01ef255e3b

02

EXECUTED GHERKIN STEP

When I sign in to the redesign as the EU manufacturer PASS

 Technical file 

   [TEST] Flok Health EU
Manufacturer  

Your work

[TEST] Flok Health EU - Wednesday 9 September

 **5**
drafts to finish

 **0**
returned for changes

 **0**
waiting on a partner

 **16**
devices, 12 released

+ Add a device

Needs you

5 drafts

 **VitaPulse Monitor**
E2E portfolio VitaPulse Monitor registration draft · 2.0

Continue

 **Flok Posture Coach**
1.0 first release

Continue

 **E2E Journey Device 1788933721006342**
Change 2

Continue

 **E2E Journey Device 1788933770899946**
2 open drafts · Change 3

Continue

Devices · 16

All 16 >

 **Flok Health**

Unreleased

 **Demo Registered Device**
2.0.0 released 9 Sept

Released

 **SecurView DX**
1.0 released 9 Sept

Released

 **AeroVent Home**
1.0 released 9 Sept

Released

 **OrthoFix Pro**
1.0 released 9 Sept

Released

 **VitaPulse Monitor**

Capture SHA-256: 241514f5cc424e915d839e844265f7671c8cb008bc34a006641154eb02e70483

03

EXECUTED GHERKIN STEP

And I open the seeded registered device PASS

 Technical file 

   [TEST] Flok Health EU
Manufacturer  

Home > Devices > Demo Registered Device

DR

Demo Registered Device Released

current 2.0.0 released 9 Sept · Basic UDI-DI 099999999910W2

Choose who

+ Start a change

Changes and releases

Release history

✓ 2.0.0 Released 9 Sept · Change 3	Delivered	Open
✓ 2.0.0 Released 9 Sept · Change 2	Delivered	Open
✓ Demo registered baseline Released 9 Sept	Delivered	Open

Current file 2.0.0 · 3 documents

Find

 Technical documentation	2 documents
happy-path-annex-vi-dataset.pdf	
happy-path-annex-vi-dataset.pdf	
 Certificates & declarations	1 document

Registration

Open

All 65 answers · ready for EUDAMED XML

Who can open it

Choose who

Only you, so far.

Identification

UDI-DI
099999999990007

Basic UDI-DI
0999999999910W2

UDI-PI
—

Capture SHA-256: d42188f4b4be129aeb96984d47846f3350a35b64ec41c5f7b038f29b0278ffa7

04

EXECUTED GHERKIN STEP

And I start a wave-two documents-only change and open its registration PASS

 Technical file 

 [TEST] Flok Health EU
Manufacturer  

Home > Demo Registered Device > Registration Back to the change

DR

Registration Unchanged

Demo Registered Device · EUDAMED device registration · 65 of 65 answered · edits ride Change 4

Not checked

Check registration

EUDAMED, by hand
1 · Produce the package.
Check the current answers. Releasing the whole change records them before its EUDAMED XML can be generated. Use the action bar below to validate and complete these answers. After release, the same action prepares the XML download.
2 · A person uploads it to EUDAMED.
A person uploads the generated XML to EUDAMED; MDIS does not submit it.
3 · Compare with EUDAMED on demand.
Compare the stored device version with EUDAMED on demand.

Check EUDAMED now

1. Device identification
13 / 13

2. Markets & countries
4 / 4

3. Clinical / intended

Device identification13 questions

Which EU regulation covers this device? Help

MDR (EU) 2017/745

EUDAMED: applicable regulation

Progress

65 of 65 · XML needs all 65

In this change

Nothing edited yet. Registered answers stay as they are.

Help

Each question shows EUDAMED's own guidance from its help button. The XML is produced here and uploaded to EUDAMED by hand; MDIS submits nothing itself.

Capture SHA-256: e635c54f29b48bb5b792a22017ac5e808f5b012b3727fa7e5297f8a2ec861dce

05

EXECUTED GHERKIN STEP

Then the wave-two MDR topic "Device identification" shows its exact current questions PASS

No visible change at this step; the already-selected topic's questions were checked

 **Technical file** 

   **[TEST] Flok Health EU** 
Manufacturer 

Home > Demo Registered Device > Registration

DR **Registration** Unchanged

Demo Registered Device · EUDAMED device registration · 65 of 65 answered · edits ride Change 4

Not checked Check registration

EUDAMED, by hand

1 · Produce the package.
Check the current answers. Releasing the whole change records them before its EUDAMED XML can be generated.
Use the action bar below to validate and complete these answers. After release, the same action prepares the XML download.

2 · A person uploads it to EUDAMED.
A person uploads the generated XML to EUDAMED; MDIS does not submit it.

3 · Compare with EUDAMED on demand.
Compare the stored device version with EUDAMED on demand.

Check EUDAMED now

1. Device Identification
13 / 13

2. Markets & countries
4 / 4

3. Clinical / intended

Device identification 13 questions

Which EU regulation covers this device?  Help MDR (EU) 2017/745

EUDAMED: applicable regulation

Progress



65 of 65 · XML needs all 65

In this change

Nothing edited yet. Registered answers stay as they are.

Help

Each question shows EUDAMED's own guidance from its help button. The XML is produced here and uploaded to EUDAMED by hand; MDIS submits nothing itself.

Capture SHA-256: e635c54f29b48bb5b792a22017ac5e808f5b012b3727fa7e5297f8a2ec861dce

06

EXECUTED GHERKIN STEP

And the wave-two MDR topic "Markets & countries" shows its exact current questions PASS

 Technical file 

 [TEST] Flok Health EU
Manufacturer  

Home > Demo Registered Device > Registration

 **Registration** Unchanged

Demo Registered Device · EUDAMED device registration · 65 of 65 answered · edits ride Change 4

Not checked

Check registration

EUDAMED, by hand
1 · Produce the package.
Check the current answers. Releasing the whole change records them before its EUDAMED XML can be generated.
Use the action bar below to validate and complete these answers. After release, the same action prepares the XML download.
2 · A person uploads it to EUDAMED.
A person uploads the generated XML to EUDAMED; MDis does not submit it.
3 · Compare with EUDAMED on demand.
Compare the stored device version with EUDAMED on demand.

Check EUDAMED now

1. Device identification
13 / 13

2. Markets & countries
4 / 4

3. Clinical / intended

Markets & countries 4 questions
Countries where the device is placed on the market  [Help](#)
EUDAMED: Member States where

AT

BE

BG

HR

CY

CZ

DE

DK

EE

EL

ES

FI

FR

Progress

65 of 65 · XML needs all 65

In this change
Nothing edited yet. Registered answers stay as they are.

Help
Each question shows EUDAMED's own guidance from its help button. The XML is produced here and uploaded to EUDAMED by hand; MDis submits nothing itself.

Capture SHA-256: c8809ca905ceac35d8da8a093f5e058977e03f78538fe4d5bc45ee66f9d3d949

07

EXECUTED GHERKIN STEP

And the wave-two MDR topic "Clinical / intended purpose" shows its exact current questions PASS

 **Technical file** 

   **[TEST] Flok Health EU** 
Manufacturer 

Home > Demo Registered Device > Registration Back to the change

DR **Registration** Unchanged
Demo Registered Device · EUDAMED device registration · 65 of 65 answered · edits ride Change 4

Not checked

Check registration

EUDAMED, by hand
1 · Produce the package.
Check the current answers. Releasing the whole change records them before its EUDAMED XML can be generated.
Use the action bar below to validate and complete these answers. After release, the same action prepares the XML download.
2 · A person uploads it to EUDAMED.
A person uploads the generated XML to EUDAMED; MDIS does not submit it.
3 · Compare with EUDAMED on demand.
Compare the stored device version with EUDAMED on demand.

Check EUDAMED now

1. Device identification
13 / 13

2. Markets & countries
4 / 4

3. Clinical / intended purpose
16 / 16

Clinical / intended purpose 16 questions

Does the product follow the Annex XVI route (a non-medical intended purpose)?  **Help**

Yes No

EUDAMED: intended purpose other than medical · MDR Annex XVI

Progress

65 of 65 · XML needs all 65

In this change
Nothing edited yet. Registered answers stay as they are.

Help
Each question shows EUDAMED's own guidance from its help button. The XML is produced here and uploaded to EUDAMED by hand; MDIS submits nothing itself.

Capture SHA-256: e68b7ba903b0748996be202bf59e2ffedf371993b05673ee011339ff88c92a5b

08

EXECUTED GHERKIN STEP

And the wave-two MDR topic "Risk class & rules" shows its exact current questions PASS

 Technical file 

   [TEST] Flok Health EU
Manufacturer  

A person uploads the generated XML to EUDAMED; MDIS does not submit it.

3 · Compare with EUDAMED on demand.
Compare the stored device version with EUDAMED on demand.

[Check EUDAMED now](#)

1. Device identification
13 / 13

2. Markets & countries
4 / 4

3. Clinical / intended purpose
16 / 16

4. Risk class & rules
3 / 3

5. Sterilisation & safety
15 / 15

6. Certificates & UDI
14 / 14

Risk class & rules 3 questions

What is the approved risk class for this device?  [Help](#)

EUDAMED: device class · MDR
Art. 51, Annex VIII

Is this Class IIb implantable device a suture, staple, dental filling, brace, crown, screw, wedge, plate, wire, pin, clip or connector?  [Help](#) *Not asked — the controlling answer does not apply.*

EUDAMED: Class IIb
implantable exception · MDR
Art. 52(4)

Does the device have critical warnings or contraindications?  [Help](#) ☐ ☒

EUDAMED: critical warnings or contraindications · Annex VI
B 23

Help

Each question shows EUDAMED's own guidance from its help button. The XML is produced here and uploaded to EUDAMED by hand; MDIS submits nothing itself.

Capture SHA-256: 0761dbdd7a21b2a51601e25a668d58b60048c72343f393cf41ea332f690fb1e9

09

EXECUTED GHERKIN STEP

And the wave-two MDR topic "Sterilisation & safety" shows its exact current questions PASS

 Technical file 

   [TEST] Flok Health EU
Manufacturer  

A person uploads the generated XML to EUDAMED; MDIS does not submit it.

3 · Compare with EUDAMED on demand.
Compare the stored device version with EUDAMED on demand.

[Check EUDAMED now](#)

1. Device identification
13 / 13

2. Markets & countries
4 / 4

3. Clinical / intended purpose
16 / 16

4. Risk class & rules
3 / 3

5. Sterilisation & safety
15 / 15

6. Certificates & UDI
14 / 14

Sterilisation & safety15 questions

Is the device supplied packaged sterile?

 Help

Yes

No

EUDAMED: device sterile state
· Annex VI B 18

Must the user sterilise the device before use?

 Help

Yes

No

EUDAMED: need for sterilisation before use ·
Annex VI B 19

Is the device labelled as single use?

 Help

Yes

No

EUDAMED: single-use status ·
Annex VI B 16

Maximum Number of Reuses Applicable

 Help

Not asked — the controlling answer does not apply.

EUDAMED: maximum number of reuses applicable

Maximum Number of Reuses

 Help

Not asked — the controlling answer does not apply.

EUDAMED: maximum number of

Help

Each question shows EUDAMED's own guidance from its help button. The XML is produced here and uploaded to EUDAMED by hand; MDIS submits nothing itself.

Capture SHA-256: 07adc9458925c52fea986dee00d844c2641a0c20daf0a15661fae124db5f041d

MDIS walkthrough · 336 / 418

 Technical file 

   [TEST] Flok Health EU
Manufacturer  

A person uploads the generated XML to EUDAMED; MDIS does not submit it.

3 · Compare with EUDAMED on demand.
Compare the stored device version with EUDAMED on demand.

[Check EUDAMED now](#)

1. Device identification
13 / 13

2. Markets & countries
4 / 4

3. Clinical / intended purpose
16 / 16

4. Risk class & rules
3 / 3

5. Sterilisation & safety
15 / 15

6. Certificates & UDI
14 / 14

Certificates & UDI14 questions

What type of certificate covers this device?
EUDAMED: certificate type · MDR Art. 56

 [Help](#) Not required for this device's regulation and risk class.

What is the certificate number and notified body?
EUDAMED: certificate number · notified body

 [Help](#) Not required for this device's regulation and risk class.

Is a UDI marked permanently on the device itself?
EUDAMED: direct marking DI · Annex VI C 4

 [Help](#)

Yes — separate direct-marking DI

Yes — same as the UDI-DI

No

Issuing Entity
EUDAMED: direct marking issuing entity

 [Help](#) Not asked — the controlling answer does not apply.

Direct Marking DI
EUDAMED: direct marking UDI-DI

 [Help](#) Not asked — the controlling answer does not apply.

Help

Each question shows EUDAMED's own guidance from its help button. The XML is produced here and uploaded to EUDAMED by hand; MDIS submits nothing itself.

Capture SHA-256: 48c3d6b5e295f97a1a2489686d21c1ef9b89d32137031a66a65c5ec4770e5cb4

MDIS walkthrough · 337 / 418

11

EXECUTED GHERKIN STEP

And the six inspected wave-two MDR topics total 65 questions PASS

No visible change at this step; the six inspected topic counts match the editor's total of 65 questions

 **Technical file** 

   **[TEST] Flok Health EU** 
Manufacturer 

A person uploads the generated XML to EUDAMED; MDIS does not submit it.

3 - Compare with EUDAMED on demand.
Compare the stored device version with EUDAMED on demand.

[Check EUDAMED now](#)

1. Device identification
13 / 13

2. Markets & countries
4 / 4

3. Clinical / intended purpose
16 / 16

4. Risk class & rules
3 / 3

5. Sterilisation & safety
15 / 15

6. Certificates & UDI
14 / 14

Certificates & UDI
14 questions

What type of certificate covers this device?  **Help** *Not required for this device's regulation and risk class.*
EUDAMED: certificate type - MDR Art. 56

What is the certificate number and notified body?  **Help** *Not required for this device's regulation and risk class.*
EUDAMED: certificate number - notified body

Is a UDI marked permanently on the device itself?  **Help** ☐ Yes — separate direct-marking DI ☒ Yes — same as the UDI-DI ☐ No
EUDAMED: direct marking DI - Annex VI C 4

Issuing Entity  **Help** *Not asked — the controlling answer does not apply.*
EUDAMED: direct marking issuing entity

Direct Marking DI  **Help** *Not asked — the controlling answer does not apply.*
EUDAMED: direct marking UDI-DI

Help

Each question shows EUDAMED's own guidance from its help button. The XML is produced here and uploaded to EUDAMED by hand; MDIS submits nothing itself.

Capture SHA-256: 48c3d6b5e295f97a1a2489686d21c1ef9b89d32137031a66a65c5ec4770e5cb4

 Technical file 

A person uploads the generated XML to EUDAMED; MDR is not submitted.

3 · Compare with EUDAMED on demand.

Compare the stored device version with EUDAMED on demand.

[Check EUDAMED now](#)

1. Device identification
13 / 13

2. Markets & countries
4 / 4

3. Clinical / intended purpose
16 / 16

4. Risk class & rules
3 / 3

5. Sterilisation & safety
15 / 15

6. Certificates & UDI
14 / 14

Device identification13 questions

Which EU regulation covers this device?

Help

MDR (EU) 2017/745

EUDAMED: applicable regulation

Trade name

Help

Not asked — the controlling answer does not apply.

EUDAMED: device trade name · Annex VI A 2.1

Basic UDI-DI

Help

099999999910W2

EUDAMED: Basic UDI-DI · Annex VI B 1

UDI-DI

Help

09999999990007

EUDAMED: UDI-DI · Annex VI B 2

Device Version

Help

E2E-1788933787609

EUDAMED: device version

Which entity issued the UDI code?

Help

GSI

HIBCC

ICCBBA

IFA

EUDAMED

EUDAMED: issuing entity · MDR Art. 27(2)

QUESTION GUIDANCE

Basic UDI-DI

Why this is asked

The family-level identifier — assigned once, never reissued per revision.

Authority field

EUDAMED: Basic UDI-DI · Annex VI B 1

What MDIS checks

The value must match the approved EUDAMED field type and any controlling answers.

Press Escape to close and return to the question.

Capture SHA-256: 31d609f48744164aa8006afed23f3128de1d019d13736f6c1f89c05709e0a063

MDIS walkthrough · 339 / 418

13

EXECUTED GHERKIN STEP

And I close wave-two guidance with Escape and verify the unchanged registration PASS

 Technical file 

   [TEST] Flok Health EU
Manufacturer 

A person uploads the generated XML to EUDAMED; MDIS does not submit it.

3 · Compare with EUDAMED on demand.

Compare the stored device version with EUDAMED on demand.

Check EUDAMED now

1. Device identification
13 / 13

2. Markets & countries
4 / 4

3. Clinical / intended purpose
16 / 16

4. Risk class & rules
3 / 3

5. Sterilisation & safety
15 / 15

6. Certificates & UDI
14 / 14

Device identification13 questions

Which EU regulation covers this device?
EUDAMED: applicable regulation
MDR (EU) 2017/745

Trade name
EUDAMED: device trade name - Annex VI A 2.1
Not asked — the controlling answer does not apply.

Basic UDI-DI
EUDAMED: Basic UDI-DI - Annex VI B 1
099999999910W2

UDI-DI
EUDAMED: UDI-DI - Annex VI B 2
09999999990007

Device Version
EUDAMED: device version
E2E-1788933787609

Which entity issued the UDI code?
EUDAMED: issuing entity - MDR Art. 27(2)
GSI HIBCC ICCBBA IFA EUDAMED

Help

Each question shows EUDAMED's own guidance from its help button. The XML is produced here and uploaded to EUDAMED by hand; MDIS submits nothing itself.

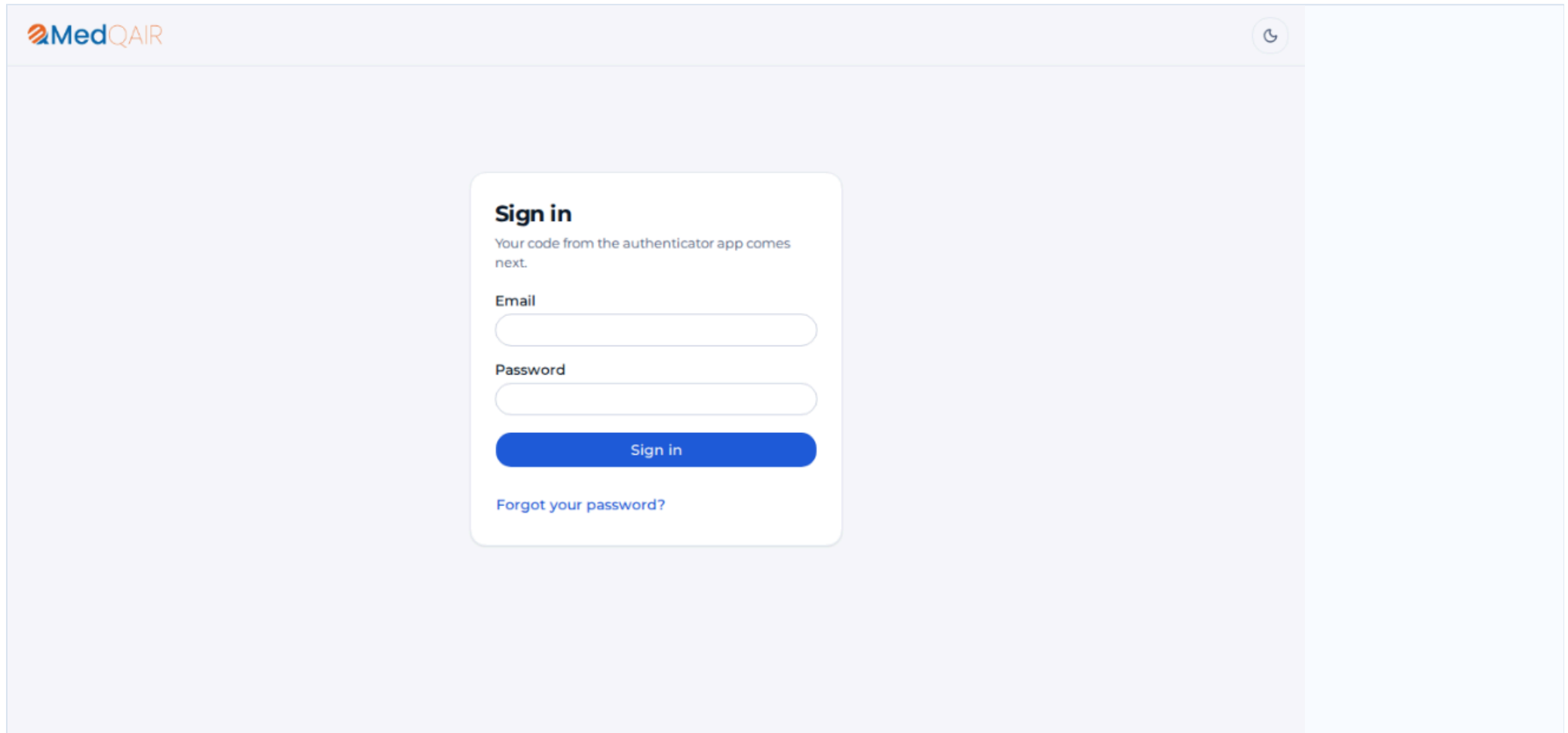
Capture SHA-256: c0c623ba8ffd11413cb1166d40e487b355ee498e533b6e22866e1d56de96409e

Reverting one of two saved answers preserves the other answer and its change diff

This proves independent saved answers and partial reversion. It does not prove the older promise that editing an answer converts a Documents only draft to Documents + registration.

01

EXECUTED GHERKIN STEP

Given the redesign sign-in page **PASS**

Capture SHA-256: 953d9a1220a1b501a0ede3a87b7d5516c6552f0e0d727f3b59246c01ef255e3b

02

EXECUTED GHERKIN STEP

When I sign in to the redesign as the EU manufacturer PASS

 Technical file 

   [TEST] Flok Health EU
Manufacturer  

Your work

[TEST] Flok Health EU - Wednesday 9 September

 **5**
drafts to finish

 **0**
returned for changes

 **0**
waiting on a partner

 **16**
devices, 12 released

Needs you5 drafts

 **VitaPulse Monitor**
E2E portfolio VitaPulse Monitor registration draft · 2.0

Continue

 **Flok Posture Coach**
1.0 first release

Continue

 **E2E Journey Device 1788933721006342**
Change 2

Continue

 **E2E Journey Device 1788933770899946**
2 open drafts · Change 3

Continue

Devices · 16All 16 >

 **Flok Health**Unreleased

 **Demo Registered Device**
2.0.0 released 9 SeptReleased

 **SecurView DX**
1.0 released 9 SeptReleased

 **AeroVent Home**
1.0 released 9 SeptReleased

 **OrthoFix Pro**
1.0 released 9 SeptReleased

 **VitaPulse Monitor**

Capture SHA-256: 241514f5cc424e915d839e844265f7671c8cb008bc34a006641154eb02e70483

03

EXECUTED GHERKIN STEP

And I open the seeded registered device PASS

 Technical file 

 TF [TEST] Flok Health EU  EE
Manufacturer

Home › Devices › Demo Registered Device

DR

Demo Registered Device Released

current 2.0.0 released 9 Sept · Basic UDI-DI 099999999910W2

Choose who

+ Start a change

Changes and releases

Release history

 **2.0.0**
Released 9 Sept · Change 3

 **2.0.0**
Released 9 Sept · Change 2

 **Demo registered baseline**
Released 9 Sept

Delivered

Open

Delivered

Open

Delivered

Open

Current file 2.0.0 · 3 documents

Find

 **Technical documentation** 2 documents

happy-path-annex-vi-dataset.pdf

happy-path-annex-vi-dataset.pdf

 **Certificates & declarations** 1 document

Registration Open

All 65 answers · ready for EUDAMED XML

Who can open it Choose who

Only you, so far.

Identification

UDI-DI
099999999990007

Basic UDI-DI
0999999999910W2

UDI-PI
—

Capture SHA-256: d42188f4b4be129aeb96984d47846f3350a35b64ec41c5f7b038f29b0278ffa7

MDIS walkthrough · 343 / 418

04

EXECUTED GHERKIN STEP

And I start a wave-two documents-only change and open its registration **PASS**

 Technical file 

 TF [TEST] Flok Health EU
Manufacturer  EE

Home > Demo Registered Device > Registration Back to the change

DR

Registration Unchanged

Demo Registered Device · EUDAMED device registration · 65 of 65 answered · edits ride Change 5

Not checked

Check registration

EUDAMED, by hand

- 1 · Produce the package.**

Check the current answers. Releasing the whole change records them before its EUDAMED XML can be generated. Use the action bar below to validate and complete these answers. After release, the same action prepares the XML download.
- 2 · A person uploads it to EUDAMED.**

A person uploads the generated XML to EUDAMED; MDIS does not submit it.
- 3 · Compare with EUDAMED on demand.**

Compare the stored device version with EUDAMED on demand.

Check EUDAMED now

1. Device identification
13 / 13

2. Markets & countries
4 / 4

3. Clinical / intended

Device identification 13 questions

Which EU regulation covers this device?  Help

EUDAMED: applicable regulation

MDR (EU) 2017/745

Progress

65 of 65 · XML needs all 65

In this change

Nothing edited yet. Registered answers stay as they are.

Help

Each question shows EUDAMED's own guidance from its help button. The XML is produced here and uploaded to EUDAMED by hand; MDIS submits nothing itself.

Capture SHA-256: 2e88ebaec34febc81ba664c6100af2cbee9ba4c2ea9e2004eadd0d05a45374d3

05

EXECUTED GHERKIN STEP

And I save independent wave-two version and reference-number answers PASS

 **Technical file** 

   **[TEST] Flok Health EU** 
Manufacturer 

1. Device identification
13 / 13 · 2 answers changed

2. Markets & countries
4 / 4

3. Clinical / intended purpose
16 / 16

4. Risk class & rules
3 / 3

5. Sterilisation & safety
15 / 15

6. Certificates & UDI
14 / 14

EUDAMED: device version

was ~~E2E-1780933787699~~ · now **Wave-two-b2bdb9a1**

Which entity issued the UDI code? 
EUDAMED: issuing entity · MDR Art. 27(2)



UDI-DI from another entity (secondary) applicable? 
EUDAMED: secondary UDI-DI applicable

UDI-DI from another entity 
EUDAMED: secondary UDI-DI
Not asked — the controlling answer does not apply.

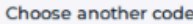
Issuing Entity 
EUDAMED: secondary UDI-DI issuing entity
Not asked — the controlling answer does not apply.

Trade Name Applicable 
EUDAMED: trade name applicable

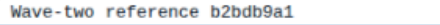
 

Nomenclature Code 
EUDAMED: nomenclature code (EMDN) · MDR Art. 26



Reference/Catalogue Number 



Capture SHA-256: 66bbe21daaddc2c3d76b2c89a0cd59f0613865111db6621d3d9b461d499c7b5f

06

EXECUTED GHERKIN STEP

Then both wave-two answers survive reload and name their carrying change PASS

MedQAIR Technical file [TEST] Flok Health EU Manufacturer

Home > Demo Registered Device > Registration

Registration Changed

Demo Registered Device · EUDAMED device registration · 65 of 65 answered · edits ride Change 5

2 answers changed — part of change [Change 5](#).

Not checked Check registration

EUDAMED, by hand

- 1 · Produce the package.**
Check the current answers. Releasing the whole change records them before its EUDAMED XML can be generated. Use the action bar below to validate and complete these answers. After release, the same action prepares the XML download.
- 2 · A person uploads it to EUDAMED.**
A person uploads the generated XML to EUDAMED; MDIS does not submit it.
- 3 · Compare with EUDAMED on demand.**
Compare the stored device version with EUDAMED on demand.

Check EUDAMED now

1. Device identification 13 / 13 · 2 answers changed

Device identification 13 questions

Which EU regulation Help

Progress

65 of 65 · XML needs all 65

In this change

Device Version
E2E-1788933787609 → Wave-two-b2bdb9a1

Reference/Catalogue Number
DEMO-REF-001 → Wave-two reference b2bdb9a1

Released with Change 5. Registered answers stay until then.

Help

Each question shows EUDAMED's own guidance from its help button. The XML is produced here and unloaded to EUDAMED by

Capture SHA-256: c50a3c21dc230a46fbb164a497aa5d08ccc1466bac120d0e0556cfdc1cfa3931

07

EXECUTED GHERKIN STEP

When I follow the wave-two banner to the change PASS

 Technical file ▼

⌂ TF [TEST] Flok Health EU ▼ EE
Manufacturer

Home › Demo Registered Device › Change 5

DR **Change 5** Draft
follows 2.0.0 released 9 Sept

Discard draft Release

📄 **Documents** 3 Find 📁 Add files

📁 Drop PDFs here · section guessed from the filename, you confirm

3 unchanged documents Show all

Ready to release? Ready

✓ **Every upload has a section.**
Settings / Review policy · Documents

✓ **Your representation for this market is confirmed.**
Who receives it · Release authority & reviewers

🌐 **Registration** Changed
2 answers differ from the registered record.
> Show 2 registration changes
Open registration

Who receives it Choose who
Nobody receives this release.

Capture SHA-256: e333211f24c01f9a2316ae18a479329473721a3386ece9e6eff9ed9af0ca2a45

08

EXECUTED GHERKIN STEP

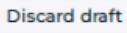
Then the wave-two Registration card mirrors both persisted answer diffs **PASS**

 Technical file 

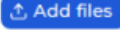
  [TEST] Flok Health EU
Manufacturer 

Home > Demo Registered Device > Change 5

 **Change 5** Draft
follows 2.0.0 released 9 Sept

 Documents 3

Find 

 Drop PDFs here · section guessed from the filename, you confirm

3 unchanged documents 

Ready to release? 

 **Every upload has a section.**
Settings / Review policy · Documents

 **Your representation for this market is confirmed.**
Who receives it · Release authority & reviewers

 **Registration** 

2 answers differ from the registered record.

 Show 2 registration changes

Device Version	Reference/Catalogue Number
E2E-178803378766	DEMO-REF-001
→	→
Wave-two-	Wave-two reference

Capture SHA-256: a53890e329671b33b9b1426e9ea6eae3145be6548f1936ff11a11a795479eb34

09

EXECUTED GHERKIN STEP

When I reopen wave-two registration and restore only the version answer PASS

 Technical file 

   [TEST] Flok Health EU
Manufacturer  

Check the current answers. Releasing the whole change records them before its EUDAMED XML can be generated. Use the action bar below to validate and complete these answers. After release, the same action prepares the XML download.

2 · A person uploads it to EUDAMED.
A person uploads the generated XML to EUDAMED; MDIS does not submit it.

3 · Compare with EUDAMED on demand.
Compare the stored device version with EUDAMED on demand.

[Check EUDAMED now](#)

1. Device identification
13 / 13 · 1 answer changed

2. Markets & countries
4 / 4

3. Clinical / intended purpose
16 / 16

4. Risk class & rules
3 / 3

5. Sterilisation & safety
15 / 15

6. Certificates & UDI
14 / 14

Device identification 13 questions

Which EU regulation covers this device?  [Help](#)
EUDAMED: applicable regulation

Trade name  [Help](#)
EUDAMED: device trade name · Annex VI A 2.1

Basic UDI-DI  [Help](#)
EUDAMED: Basic UDI-DI · Annex VI B 1

UDI-DI  [Help](#)
EUDAMED: UDI-DI · Annex VI B 2

Device Version  [Help](#)
EUDAMED: device version

Reference/ change number

Released with Change 5. Registered answers stay until then.

Help
Each question shows EUDAMED's own guidance from its help button. The XML is produced here and uploaded to EUDAMED by hand; MDIS submits nothing itself.

Capture SHA-256: 04b09af586dde2de457e086cfadcc73ef980a3dfb359521191f1f296e2ca99b1

10

EXECUTED GHERKIN STEP

Then only the wave-two reference-number diff remains in the editor and change card PASS

 Technical file ▼

 TF [TEST] Flok Health EU ▼ EE

Manufacturer

Home › Demo Registered Device › Change 5

DR **Change 5** Draft
follows 2.0.0 released 9 Sept

Discard draft Release

Documents 3 Find Add files

Drop PDFs here · section guessed from the filename, you confirm

3 unchanged documents Show all

Ready to release? Ready

✓ **Every upload has a section.**
Settings / Review policy · Documents

✓ **Your representation for this market is confirmed.**
Who receives it · Release authority & reviewers

Registration Changed

1 answer differs from the registered record.

▼ **Show 1 registration change**

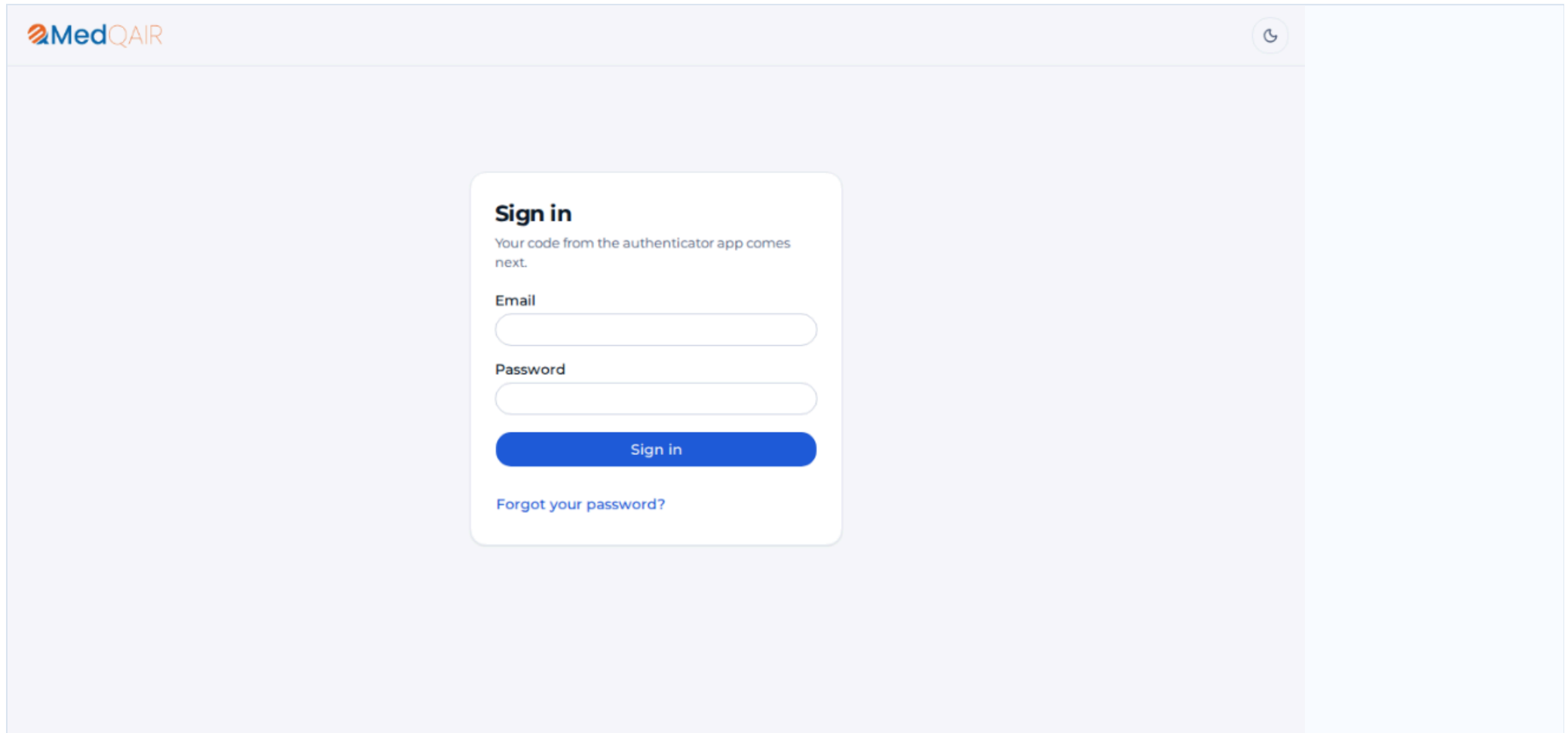
Reference/Catalogue Number
~~DEMO-REF-001~~
→
Wave-two reference

Capture SHA-256: b55ee16656e71ca8ba26e20e46309058e1494acd97079ed7f8bc58246c7ceb0c

A batch deletion uses one optional reason for both released documents

01

EXECUTED GHERKIN STEP

Given the redesign sign-in page **PASS**

Capture SHA-256: 953d9a1220a1b501a0ede3a87b7d5516c6552f0e0d727f3b59246c01ef255e3b

02

EXECUTED GHERKIN STEP

When I sign in to the redesign as a manufacturer **PASS**

 Technical file 

   [TEST] Northstar Medical Im...  

Your work

[TEST] Northstar Medical Imaging · Wednesday 9 September

 **12**
drafts to finish

 **0**
returned for changes

 **0**
waiting on a partner

 **41**
devices, 6 released

 Add a device

Needs you

12 drafts

 **Northstar VitalSync Patient Monitor**
1.1 labelling update 

 **Northstar SonoLite Handheld Ultrasound**
1.0 first release 

 **Northstar CardioMesh Coronary Stent**
1.0 first release 

 **Northstar LumaDerm Phototherapy Lamp**
Change 1 · first release 

 **E2E Journey Device 1788933641806128**
Change 1 · 1.0.0 · first release 

 **E2E Journey Device 1788933703671839**
Change 1 · 1.0.0 · first release 

Devices · 41

 Name, UDI-DI or Basic UDI-DI

 **PulseView AR Validation ...** 

 **AtlasView PRRC Validatio...** 

 **AtlasView AR Verification ...** 

 **AtlasView AR Validation ...** 

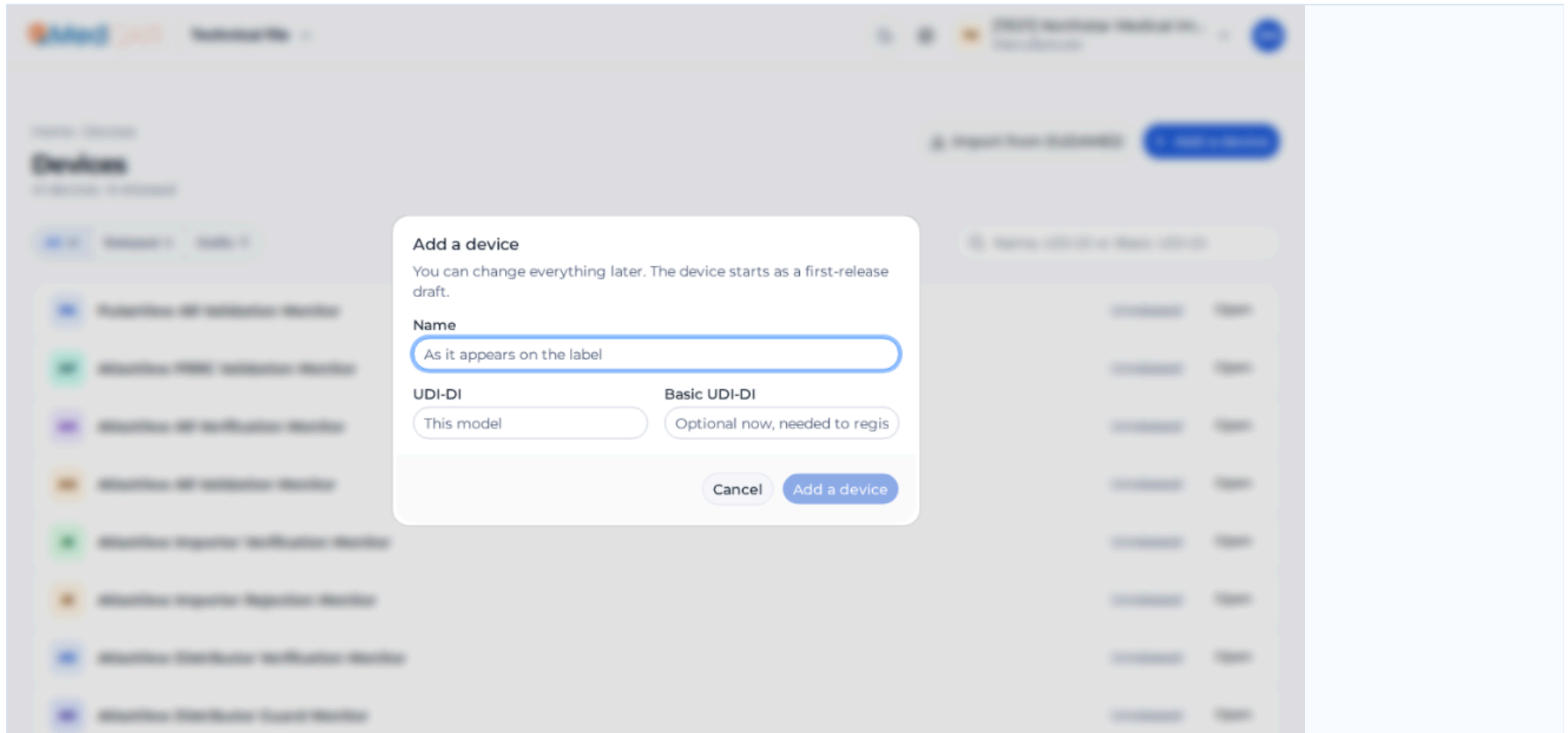
 **AtlasView Importer Verifi...** 

 **AtlasView Importer Rejec...** 

Capture SHA-256: 2635fc1c93d52d0a66885acc0e57e65bb091a15eb467f6eff4e140170fab9ef9

03

EXECUTED GHERKIN STEP

And I open the redesign's add-device form **PASS**

Capture SHA-256: af4466d07de749c4e8534f0f00c2c9e60a447201cfb93b39d4dc502cfd250844

04

EXECUTED GHERKIN STEP

And I submit a device with a unique name and UDI-DI PASS

 Technical file 

   [TEST] Northstar Medical Im...  

Home > Devices > E2E Journey Device 1788933908800991

 **E2E Journey Device 1788933908800991** Unreleased
not released yet · Basic UDI-DI —

Choose who 

Changes and releases

No changes yet.

Registration Open

Not started. EUDAMED needs every answer.

Who can open it Choose who

Only you, so far.

Identification

UDI-DI
E2E-1788933908800991

Basic UDI-DI
—

UDI-PI
—

Capture SHA-256: 7fcbd0fe5a80a1518765d2f04fbbf6163ab6e6aac5a6c77ccdf8e86a69076aca

05

EXECUTED GHERKIN STEP

And I start production version "wave 2 batch deletion baseline" PASS

 Technical file 

  [TEST] Northstar Medical Im...  

Home > E2E Journey Device 1788933908800991 > Change 1

 **Change 1** Draft

Version wave 2 batch deletion baseline Rename

 **Documents** 0

Find  Add files

 Drop PDFs here · section guessed from the filename, you confirm

No documents yet.

Ready to release? Ready

 **Every upload has a section.**
Settings / Review policy · Documents

 **This device's target market is not recorded — add its EUDAMED registration from the device's Registration page; the registration records the market.**
Who receives it · Release authority & reviewers · recommended — you can still release
MDIS compares your organisation's country (from its SRN) with this device's market. Your representative is appointed under Who receives it — a partner you are already connected to at once, a new one once they accept the invitation.
Confirming records that the appointment covers this market.
[Open Who receives it](#)

Capture SHA-256: 042205b476ea0c966d9e8ea6b82ec8933369d478051fa6826488ef45c17f7a45

06

EXECUTED GHERKIN STEP

And I complete the release's market facts PASS

 Technical file 

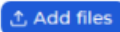
  [TEST] Northstar Medical Im...  

Home > E2E Journey Device 1788933908800991 > Change 1

 **Change 1** Draft

Version wave 2 batch deletion baseline Rename

 Documents 0

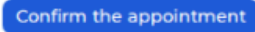
Find 

 Drop PDFs here · section guessed from the filename, you confirm

No documents yet.

Ready to release? Ready

 Every upload has a section.
Settings / Review policy · Documents

 Your organisation's country is not this device's market, so the release needs a confirmed authorised representative — appoint one under Who receives it, then confirm.
Who receives it · Release authority & reviewers · recommended — you can still release
MDIS compares your organisation's country (from its SRN) with this device's market. Your representative is appointed under Who receives it — a partner you are already connected to at once, a new one once they accept the invitation. Confirming records that the appointment covers this market.

[Open Who receives it](#)

Capture SHA-256: 81ff200f93826737c732dcf307189c0caf47d46afaa8ef199fb68cffe9b23199

07

EXECUTED GHERKIN STEP

And I ensure the current release has two documents PASS

 Technical file 

  [TEST] Northstar Medical Im...  

Home > E2E Journey Device 1788933908800991 > Change 1

 **Change 1** Draft

Version wave 2 batch deletion baseline Rename

 **Documents** 2 · 2 changed  Add files

 Drop PDFs here · section guessed from the filename, you confirm

 IFU & labelling 2 documents

☐

multi-eo-product-label.pdf
New

 ...

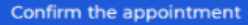
☐

eifu-multilingual.pdf
New

 ...

Ready to release? Ready

 **Every upload has a section.**
Settings / Review policy · Documents

 **Your organisation's country is not this device's market, so the release needs a confirmed authorised representative — appoint one under Who receives it, then confirm.**
Who receives it · Release authority & reviewers · recommended — you can still release
MDIS compares your organisation's country (from its SRN) with this device's market. Your representative is appointed under Who receives it — a partner you are already connected to at once, a new one once they accept the invitation. Confirming records that the appointment covers this market.
 [Open Who receives it](#)

Capture SHA-256: 8631444ba79f870b20d3ebc0b420e2ac1d8415fdfce93422f1c774a42a1b4e7a

08

EXECUTED GHERKIN STEP

And I press Release once PASS

 Technical file 

  [TEST] Northstar Medical Im...  

Home > E2E Journey Device 1788933908800991 > Change 1

 **Change 1** Draft

Version wave 2 batch deletion baseline Rename

 **Documents** 2 · 2 changed Find Add files

 Drop PDFs here · section guessed from the filename, you confirm

 **IFU & labelling** 2 documents

☐

multi-eo-product-label.pdf
New

 ...

☐

eifu-multilingual.pdf
New

 ...

Ready to release? Ready



Every upload has a section.
Settings / Review policy · Documents



Your organisation's country is not this device's market, so the release needs a confirmed authorised representative — appoint one under Who receives it, then confirm.
Who receives it · Release authority & reviewers · recommended — you can still release
MDIS compares your organisation's country (from its SRN) with this device's market. Your representative is appointed under Who receives it — a partner you are already connected to at once, a new one once they accept the invitation. Confirming records that the appointment covers this market.
Confirm the appointment
[Open Who receives it](#)

Capture SHA-256: d1e675aaa008ce8df6f2ba3968c945a3633bc444f63ccd15ae3d18fca1bcabcf

09

EXECUTED GHERKIN STEP

Then the release is delivered immediately PASS

 **Technical file** 

 **TN** **[TEST] Northstar Medical Im...**  **EM**

Home › E2E Journey Device 1788933908800991 › Change 1

Delivered to the frozen recipient set

 **Change 1** Delivered
Version wave 2 batch deletion baseline on the market since 9 Sept

 **Documents** 2 · 2 changed · frozen as released

 **IFU & labelling**

2 documents

 multi-eo-product-label.pdf
New

 ...

 eifu-multilingual.pdf
New

 ...

 **Registration** Incomplete

33 of 65 answers · EUDAMED XML needs all 65 · not needed to release

Answer remaining 32

Open registration

Who receives it Choose who

Nobody receives this release.

 **Delivery**

Delivered on 2026-09-09.

Summary

Version Documents

wave 2 batch 2

Capture SHA-256: c230009b434c74e37e17e079b73e15b66f6d410cc0328745b539901d6d00f2fd

10

EXECUTED GHERKIN STEP

When I go back to the device PASS

 Technical file 

 TN [TEST] Northstar Medical Im...  EM

Home > Devices > E2E Journey Device 1788933908800991

 **E2E Journey Device 1788933908800991** Released
current wave 2 batch deletion baseline released 9 Sept · Basic UDI-DI E2EBASIC178893391020919

Choose who [+ Start a change](#)

Changes and releases

Release history

 **wave 2 batch deletion baseline**
Released 9 Sept · Change 1

Delivered Open

Current file wave 2 batch deletion baseline · 2 documents

Find

 **IFU & labelling** 2 documents

multi-eo-product-label.pdf

eifu-multilingual.pdf

Registration Open

33 of 65 answers · EUDAMED XML needs all 65

Who can open it Choose who

Only you, so far.

Identification

UDI-DI
E2E-1788933908800991

Basic UDI-DI
E2EBASIC178893391020919

UDI-PI
—

Capture SHA-256: 9d2da637bf8a3c0d90126fb1fc942334dd14f28f6f80bf58fc710c6b49679ded

11

EXECUTED GHERKIN STEP

And I start a follow-up change PASS

 Technical file 

  [TEST] Northstar Medical Im...  

Home › E2E Journey Device 1788933908800991 › Change 2

 **Change 2** Draft
follows wave 2 batch deletion baseline released 9 Sept

Discard draft

Release

 Documents 2

Find

Add files

Drop PDFs here · section guessed from the filename, you confirm

2 unchanged documents

Show all

Ready to release? Ready

✓ Every upload has a section.
Settings / Review policy · Documents

⚠ Your organisation's country is not this device's market, so the release needs a confirmed authorised representative — appoint one under Who receives it, then confirm.
Who receives it · Release authority & reviewers · recommended — you can still release
MDIS compares your organisation's country (from its SRN) with this device's market. Your representative is appointed under Who receives it — a partner you are already connected to at once, a new one once they accept the invitation. Confirming records that the appointment covers this market.

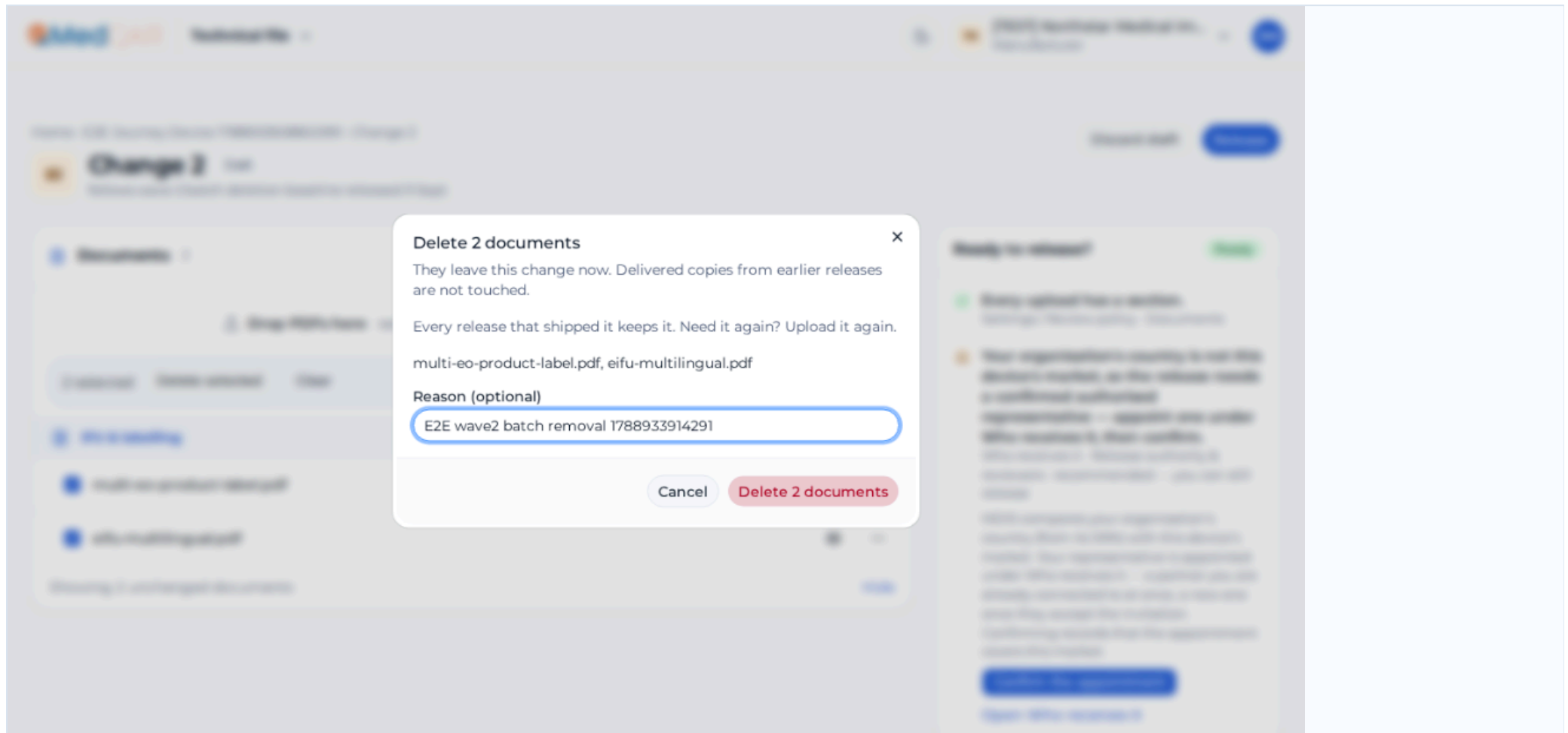
Confirm the appointment

Open Who receives it

Capture SHA-256: c9356c9312526f2274f4cb060c9e66f531a6851ebefb9a3ed9c6b7c0d38ba4e

12

EXECUTED GHERKIN STEP

When I select two released documents for one batch deletion **PASS**

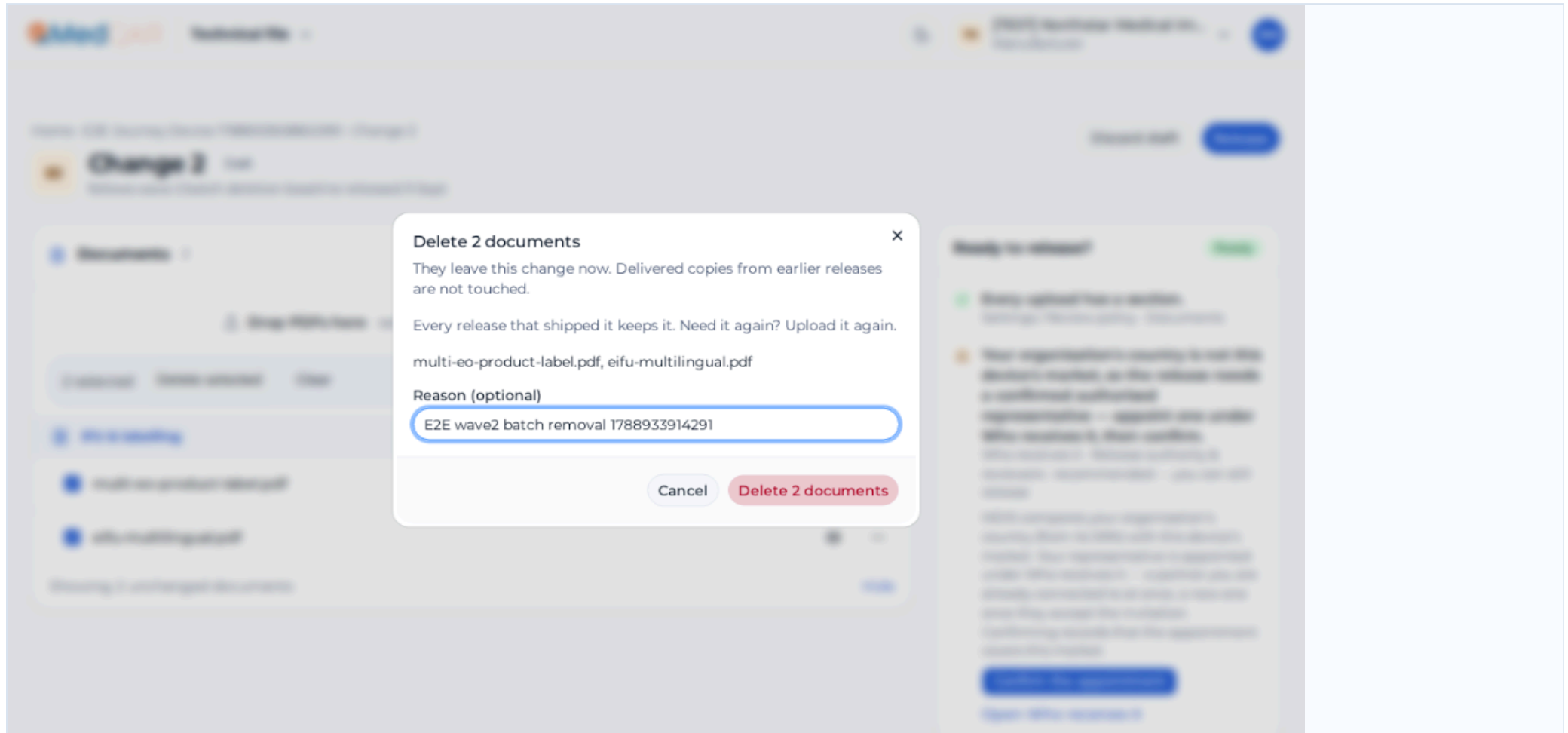
Capture SHA-256: 343c05d1f4fdeace56a8eca58e6a5ba840effa8be09976ec07c3bc052c0a0562

13

EXECUTED GHERKIN STEP

Then the batch dialog asks once for an optional reason PASS

The already-open batch deletion dialog remained visible while its one optional reason and two selected documents were checked.



Capture SHA-256: 343c05d1f4fdeace56a8eca58e6a5ba840effa8be09976ec07c3bc052c0a0562

14

EXECUTED GHERKIN STEP

When I confirm the batch deletion PASS

 Technical file 

  [TEST] Northstar Medical Im...  

Home > E2E Journey Device 1788933908800991 > Change 2

 **Change 2** Draft
follows wave 2 batch deletion baseline released 9 Sept

Documents 0

Find

Add files

Drop PDFs here · section guessed from the filename, you confirm

Removed in this change

2 documents

multi-eo-product-label.pdf

Removed at release — delivered copies stay — E2E wave2 batch removal 1788933914291

—

eifu-multilingual.pdf

Removed at release — delivered copies stay — E2E wave2 batch removal 1788933914291

—

Ready to release?

Ready

✓ Every upload has a section.

Settings / Review policy · Documents

⚠ Your organisation's country is not this device's market, so the release needs a confirmed authorised representative — appoint one under Who receives it, then confirm.

Who receives it · Release authority & reviewers · recommended — you can still release

MDIS compares your organisation's country (from its SRN) with this device's market. Your representative is appointed under Who receives it — a partner you are already connected to at once, a new one once they accept the invitation. Confirming records that the appointment covers this market.

Confirm the appointment

Open Who receives it

Capture SHA-256: f7ccbce15b24f5764e42b4f3bbacdd5c051812c7bfbf7de537b50f55e5a43c0a

15 EXECUTED GHERKIN STEP
Then the batch deletion records one optional reason for both documents PASS

No visible change at this step; asserted through the API read

 **Technical file** 

 TN **[TEST] Northstar Medical Im...**  EM

Home > E2E Journey Device 1788933908800991 > Change 2

 **Change 2** Draft

follows wave 2 batch deletion baseline released 9 Sept

 **Documents** 0

 Add files

 Drop PDFs here · section guessed from the filename, you confirm

 **Removed in this change**

2 documents

multi-eo-product-label.pdf

Removed at release — delivered copies stay — E2E wave2 batch removal 1788933914291

—

eifu-multilingual.pdf

Removed at release — delivered copies stay — E2E wave2 batch removal 1788933914291

—

Ready to release? Ready

 **Every upload has a section.**
Settings / Review policy · Documents

 **Your organisation's country is not this device's market, so the release needs a confirmed authorised representative — appoint one under Who receives it, then confirm.**
Who receives it · Release authority & reviewers · recommended — you can still release
MDIS compares your organisation's country (from its SRN) with this device's market. Your representative is appointed under Who receives it — a partner you are already connected to at once, a new one once they accept the invitation. Confirming records that the appointment covers this market.

Confirm the appointment

Open Who receives it

Capture SHA-256: f7ccbce15b24f5764e42b4f3bbacdd5c051812c7bf7de537b50f55e5a43c0a

MDIS walkthrough · 365 / 418

16

EXECUTED GHERKIN STEP

And the batch deletion remains absent after a fresh release reload PASS*No visible change at this step; asserted through the API read*

 **Technical file** 

  **[TEST] Northstar Medical Im...**  

Home > E2E Journey Device 1788933908800991 > Change 2

 **Change 2** Draft
follows wave 2 batch deletion baseline released 9 Sept

 **Documents** 0  **Add files**

 **Drop PDFs here** · section guessed from the filename, you confirm

 **Removed in this change** 2 documents

multi-eo-product-label.pdf
Removed at release — delivered copies stay — E2E wave2 batch removal 1788933914291

—

eifu-multilingual.pdf
Removed at release — delivered copies stay — E2E wave2 batch removal 1788933914291

—

Ready to release? Ready

 **Every upload has a section.**
Settings / Review policy · Documents

 **Your organisation's country is not this device's market, so the release needs a confirmed authorised representative — appoint one under Who receives it, then confirm.**
Who receives it · Release authority & reviewers · recommended — you can still release

MDIS compares your organisation's country (from its SRN) with this device's market. Your representative is appointed under Who receives it — a partner you are already connected to at once, a new one once they accept the invitation. Confirming records that the appointment covers this market.

 **Confirm the appointment**
[Open Who receives it](#)

Capture SHA-256: f7ccbce15b24f5764e42b4f3bbacdd5c051812c7bf7de537b50f55e5a43c0a

17

EXECUTED GHERKIN STEP

When I discard the current documents-screen draft PASS

 Technical file 

 TN [TEST] Northstar Medical Im...  EM

Home > Devices > E2E Journey Device 1788933908800991

 **E2E Journey Device 1788933908800991** Released
current wave 2 batch deletion baseline released 9 Sept · Basic UDI-DI E2EBASIC178893391020919

Choose who [+ Start a change](#)

Changes and releases

Release history

 **wave 2 batch deletion baseline**
Released 9 Sept · Change 1 Delivered [Open](#)

Current file wave 2 batch deletion baseline · 2 documents

[Find](#)

 **IFU & labelling** 2 documents

multi-eo-product-label.pdf

eifu-multilingual.pdf

Registration [Open](#)

33 of 65 answers · EUDAMED XML needs all 65

Who can open it [Choose who](#)

Only you, so far.

Identification

UDI-DI
E2E-1788933908800991

Basic UDI-DI
E2EBASIC178893391020919

UDI-PI
—

Capture SHA-256: ddb5e0468341dd94d38fd8602904dc6dcf3acf524d85a75e2238e44b6600e70b

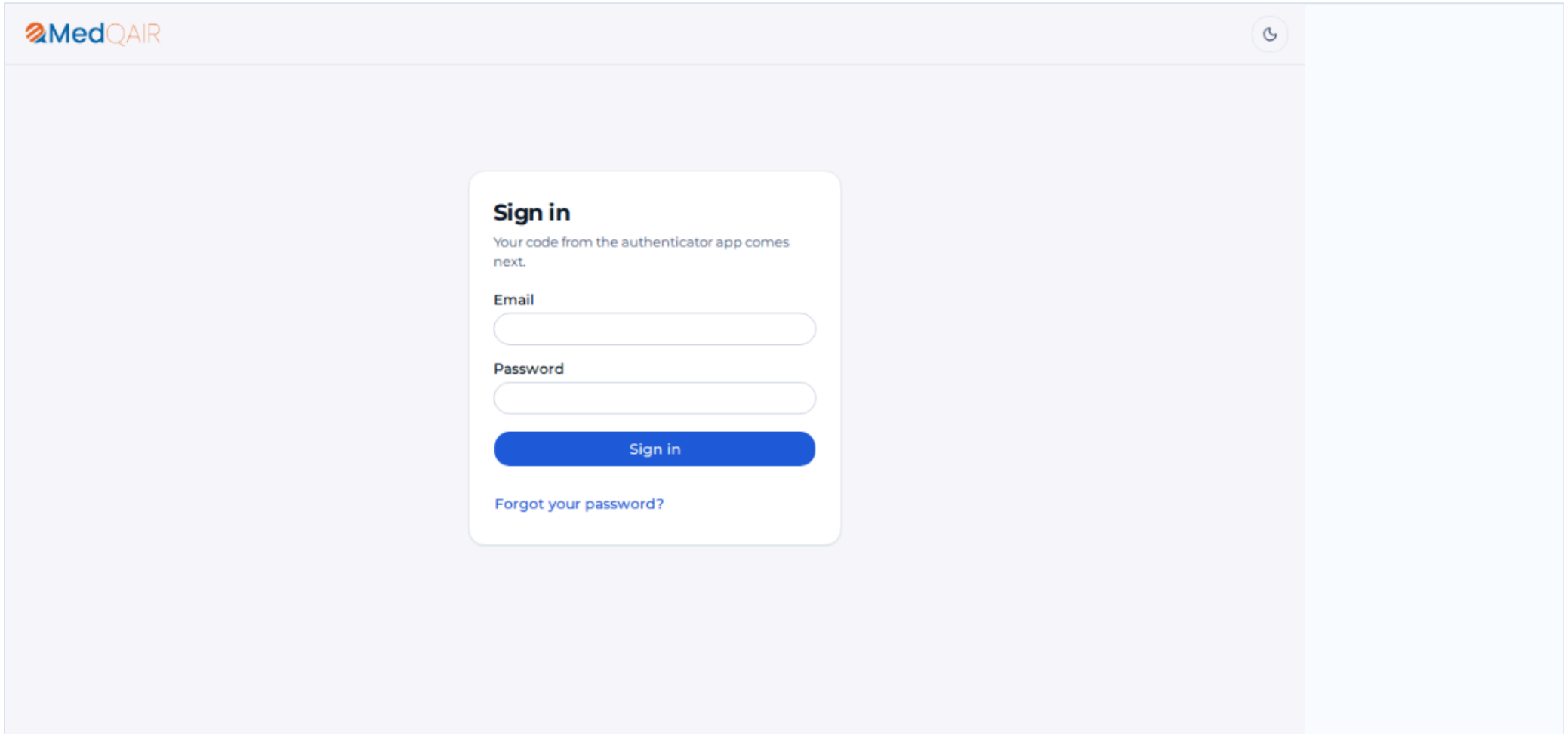
Show all and Hide all preserve unchanged document identities

The disclosure and persisted identities are exercised here. Pulling a document into the change by executing Replace remains outside this journey.

01

EXECUTED GHERKIN STEP

Given the redesign sign-in page **PASS**



Capture SHA-256: 953d9a1220a1b501a0ede3a87b7d5516c6552f0e0d727f3b59246c01ef255e3b

02

EXECUTED GHERKIN STEP

When I sign in to the redesign as a manufacturer **PASS**

 Technical file 

   [TEST] Northstar Medical Im...  

Your work

[TEST] Northstar Medical Imaging · Wednesday 9 September

 **12**
drafts to finish

 **0**
returned for changes

 **0**
waiting on a partner

 **42**
devices, 7 released

 Add a device

Needs you

12 drafts

 **NS**

Northstar SonoLite Handheld Ultrasound
1.0 first release

Continue

 **NV**

Northstar VitalSync Patient Monitor
1.1 labelling update

Continue

 **NC**

Northstar CardioMesh Coronary Stent
1.0 first release

Continue

 **NL**

Northstar LumaDerm Phototherapy Lamp
Change 1 · first release

Continue

 **E**

E2E Journey Device 1788933641806128
Change 1 · 1.0.0 · first release

Continue

 **E**

E2E Journey Device 1788933703671839
Change 1 · 1.0.0 · first release

Continue

Devices · 42

All 42 >

 **PA**

PulseView AR Validation ...

Unreleased

 **AA**

AtlasView AR Verification ...

Unreleased

 **AA**

AtlasView AR Validation ...

Unreleased

 **AI**

AtlasView Importer Verifi...

Unreleased

 **AI**

AtlasView Importer Rejec...

Unreleased

 **AD**

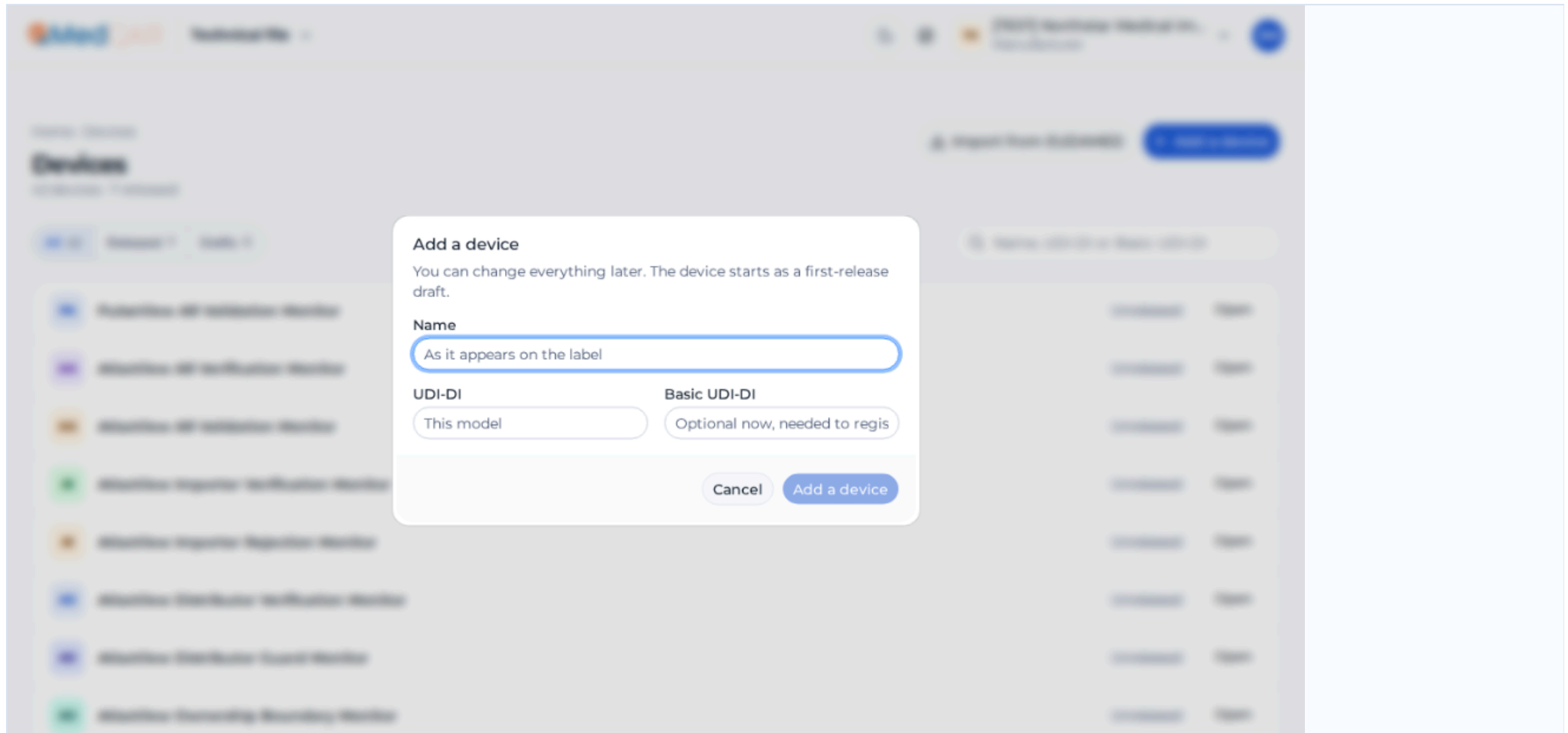
AtlasView Distributor Veri...

Unreleased

Capture SHA-256: d73b4b4cc37339616d9c4b5bf8666431f9f366ff21049751bfadddb65c4d9585

03

EXECUTED GHERKIN STEP

And I open the redesign's add-device form **PASS**

Capture SHA-256: f4298ef2d0712cffc3a9a660db72141b00c5ff00f117950be041c243a8c28420

04

EXECUTED GHERKIN STEP

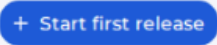
And I submit a device with a unique name and UDI-DI PASS

 Technical file 

  [TEST] Northstar Medical Im...  

Home > Devices > E2E Journey Device 1788933917911580

 **E2E Journey Device 1788933917911580** Unreleased
not released yet · Basic UDI-DI —

Choose who 

Changes and releases

No changes yet.

Registration Open

Not started. EUDAMED needs every answer.

Who can open it Choose who

Only you, so far.

Identification

UDI-DI
E2E-1788933917911580

Basic UDI-DI
—

UDI-PI
—

Capture SHA-256: 498cfdd33f0fc6f5c2cc775d3bda7f4b0f710a04ddb8ec7c726d9f6f9dc6c689

05

EXECUTED GHERKIN STEP

And I start production version "wave 2 unchanged baseline" PASS

 Technical file 

 TN [TEST] Northstar Medical Im...  EM

Home › E2E Journey Device 1788933917911580 › Change 1

 **Change 1** Draft

Version wave 2 unchanged baseline Rename

 Documents 0

 Add files

 Drop PDFs here · section guessed from the filename, you confirm

No documents yet.

Ready to release? Ready

 Every upload has a section.
Settings / Review policy · Documents

 This device's target market is not recorded — add its EUDAMED registration from the device's Registration page; the registration records the market.
Who receives it · Release authority & reviewers · recommended — you can still release
MDIS compares your organisation's country (from its SRN) with this device's market. Your representative is appointed under Who receives it — a partner you are already connected to at once, a new one once they accept the invitation.
Confirming records that the appointment covers this market.
[Open Who receives it](#)

Capture SHA-256: 6bf3c1d1bff3ad8c4d2f827364c8b89bf38800056198167ee1a2f7a0fddf8a55

06

EXECUTED GHERKIN STEP

And I complete the release's market facts PASS

 Technical file 

  [TEST] Northstar Medical Im...  

Home > E2E Journey Device 1788933917911580 > Change 1

 **Change 1** Draft

Version wave 2 unchanged baseline Rename

 **Documents** 0

 Add files

 Drop PDFs here · section guessed from the filename, you confirm

No documents yet.

Ready to release? Ready

 **Every upload has a section.**
Settings / Review policy · Documents

 **Your organisation's country is not this device's market, so the release needs a confirmed authorised representative — appoint one under Who receives it, then confirm.**
Who receives it · Release authority & reviewers · recommended — you can still release
MDIS compares your organisation's country (from its SRN) with this device's market. Your representative is appointed under Who receives it — a partner you are already connected to at once, a new one once they accept the invitation. Confirming records that the appointment covers this market.
Confirm the appointment
[Open Who receives it](#)

Capture SHA-256: 3f307b79ccf2d6fee0b46a9cfc2726ac4ce99c788845cee7d1602bc024fc8f1f

07

EXECUTED GHERKIN STEP

And I ensure the current release has two documents PASS

 Technical file 

 TN [TEST] Northstar Medical Im...  EM

Home › E2E Journey Device 1788933917911580 › Change 1

 **Change 1** Draft

Version wave 2 unchanged baseline Rename

 **Documents** 2 · 2 changed

 Add files

 Drop PDFs here · section guessed from the filename, you confirm

 IFU & labelling

2 documents

☐

eifu-multilingual.pdf

New



...

☐

multi-eo-product-label.pdf

New



...

Ready to release? Ready



Every upload has a section.
Settings / Review policy · Documents



Your organisation's country is not this device's market, so the release needs a confirmed authorised representative — appoint one under Who receives it, then confirm.
Who receives it · Release authority & reviewers · recommended — you can still release
MDIS compares your organisation's country (from its SRN) with this device's market. Your representative is appointed under Who receives it — a partner you are already connected to at once, a new one once they accept the invitation. Confirming records that the appointment covers this market.

Confirm the appointment

Open Who receives it

Capture SHA-256: 247535635aea8d7ba77e687571a30100a5042e8f6b1effe8cc8254b624ff164c

08

EXECUTED GHERKIN STEP

And I press Release once **PASS**

 Technical file 

  [TEST] Northstar Medical Im...  

Home › E2E Journey Device 1788933917911580 › Change 1

 **Change 1** Draft

Version wave 2 unchanged baseline Rename

 **Documents** 2 · 2 changed Find Add files

 Drop PDFs here · section guessed from the filename, you confirm

 IFU & labelling 2 documents

☐ eifu-multilingual.pdf New  ...

☐ multi-eo-product-label.pdf New  ...

Ready to release? Ready

 **Every upload has a section.**
Settings / Review policy · Documents

 **Your organisation's country is not this device's market, so the release needs a confirmed authorised representative — appoint one under Who receives it, then confirm.**
Who receives it · Release authority & reviewers · recommended — you can still release
MDIS compares your organisation's country (from its SRN) with this device's market. Your representative is appointed under Who receives it — a partner you are already connected to at once, a new one once they accept the invitation. Confirming records that the appointment covers this market.
Confirm the appointment
[Open Who receives it](#)

Capture SHA-256: 9b3afe0cffd0c35c53ef75a6b19712f5a682c388a86f2f38cf991dab3cb27e58

09

EXECUTED GHERKIN STEP

Then the release is delivered immediately PASS

 **Technical file** 

  **[TEST] Northstar Medical Im...**  

Home › E2E Journey Device 1788933917911580 › Change 1

Delivered to the frozen recipient set

 **Change 1** Delivered
Version wave 2 unchanged baseline on the market since 9 Sept

 **Documents** 2 · 2 changed · frozen as released

 **IFU & labelling** 2 documents

 eifu-multilingual.pdf  ...
New

 multi-eo-product-label.pdf  ...
New

 **Registration** Incomplete
33 of 65 answers · EUDAMED XML needs all 65 · not needed to release
Answer remaining 32
Open registration

Who receives it Choose who
Nobody receives this release.

 **Delivery**
Delivered on 2026-09-09.

Summary

Version	Documents
wave 2 unchanged	2

Capture SHA-256: 93917361fcaef1b504bc0bf5665fd8fe4f99982ff52e4a2cf1c4dbc80aacab88

10

EXECUTED GHERKIN STEP

When I go back to the device PASS

 Technical file 

 TN [TEST] Northstar Medical Im...  EM

Home > Devices > E2E Journey Device 1788933917911580

 **E2E Journey Device 1788933917911580** Released
current wave 2 unchanged baseline released 9 Sept · Basic UDI-DI E2EBASIC17889339190855

Choose who [+ Start a change](#)

Changes and releases

Release history

 **wave 2 unchanged baseline**
Released 9 Sept · Change 1 Delivered [Open](#)

Current file wave 2 unchanged baseline · 2 documents

 **IFU & labelling** 2 documents

eifu-multilingual.pdf

multi-eo-product-label.pdf

Registration [Open](#)

33 of 65 answers · EUDAMED XML needs all 65

Who can open it [Choose who](#)

Only you, so far.

Identification

UDI-DI
E2E-1788933917911580

Basic UDI-DI
E2EBASIC17889339190855

UDI-PI
—

Capture SHA-256: 85029357b86fe510659fd53b6ea65f3e4c9f9cd4f10061d6acac1d5f30b809ed

11

EXECUTED GHERKIN STEP

And I start a follow-up change PASS

 Technical file ▼

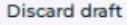
 TN [TEST] Northstar Medical Im... ▼ EM

Manufacturer

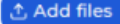
Home › E2E Journey Device 1788933917911580 › Change 2

 **Change 2** Draft

follows wave 2 unchanged baseline released 9 Sept

 Documents 2



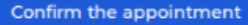
 Drop PDFs here · section guessed from the filename, you confirm

2 unchanged documents

[Show all](#)

Ready to release? Ready

 Every upload has a section.
Settings / Review policy · Documents

 Your organisation's country is not this device's market, so the release needs a confirmed authorised representative — appoint one under Who receives it, then confirm.
Who receives it · Release authority & reviewers · recommended — you can still release
MDIS compares your organisation's country (from its SRN) with this device's market. Your representative is appointed under Who receives it — a partner you are already connected to at once, a new one once they accept the invitation. Confirming records that the appointment covers this market.

[Open Who receives it](#)

Capture SHA-256: e7fc750f130a7a2c7099e0db2e33eaae3a63030869a0d0c3344d841f363eae02

12

EXECUTED GHERKIN STEP

When I expand and collapse the unchanged document group PASS

 Technical file 

  [TEST] Northstar Medical Im...  

Home > E2E Journey Device 1788933917911580 > Change 2

 **Change 2** Draft
follows wave 2 unchanged baseline released 9 Sept

Discard draft Release

 Documents 2  Add files

 Drop PDFs here · section guessed from the filename, you confirm

 IFU & labelling 2 documents

☐ eifu-multilingual.pdf  ...

☐ multi-eo-product-label.pdf  ...

Showing 2 unchanged documents [Hide](#)

Ready to release? Ready

 Every upload has a section.
Settings / Review policy · Documents

 Your organisation's country is not this device's market, so the release needs a confirmed authorised representative — appoint one under Who receives it, then confirm.
Who receives it · Release authority & reviewers · recommended — you can still release
MDIS compares your organisation's country (from its SRN) with this device's market. Your representative is appointed under Who receives it — a partner you are already connected to at once, a new one once they accept the invitation. Confirming records that the appointment covers this market.
[Confirm the appointment](#)
[Open Who receives it](#)

Capture SHA-256: 3ab4962606ba0919fbea3d179cd11f1076c8abec059acc9fcd338ee0a4122c65

13

EXECUTED GHERKIN STEP

Then the unchanged document identities survive the disclosure cycle and reload PASS

Final picture unchanged; the unchanged document group was re-expanded after reload with the same persisted identities.

 **Technical file** 

 **TN** [TEST] Northstar Medical Im...  **EM**

Home > E2E Journey Device 1788933917911580 > Change 2

 **Change 2** Draft
follows wave 2 unchanged baseline released 9 Sept

 **Documents** 2

 Add files

 Drop PDFs here · section guessed from the filename, you confirm

 **IFU & labelling**

2 documents

☐ eifu-multilingual.pdf

 ...

☐ multi-eo-product-label.pdf

 ...

Showing 2 unchanged documents Hide

Ready to release? Ready

 **Every upload has a section.**
Settings / Review policy · Documents

 **Your organisation's country is not this device's market, so the release needs a confirmed authorised representative — appoint one under Who receives it, then confirm.**
Who receives it · Release authority & reviewers · recommended — you can still release
MDIS compares your organisation's country (from its SRN) with this device's market. Your representative is appointed under Who receives it — a partner you are already connected to at once, a new one once they accept the invitation. Confirming records that the appointment covers this market.

Confirm the appointment

Open Who receives it

Capture SHA-256: 3ab4962606ba0919fbea3d179cd11f1076c8abec059acc9fcd338ee0a4122c65

14

EXECUTED GHERKIN STEP

When I discard the current documents-screen draft PASS

 Technical file 

 TN [TEST] Northstar Medical Im...  EM

Home > Devices > E2E Journey Device 1788933917911580

 **E2E Journey Device 1788933917911580** Released
current wave 2 unchanged baseline released 9 Sept · Basic UDI-DI E2EBASIC17889339190855

Choose who [+ Start a change](#)

Changes and releases

Release history

 **wave 2 unchanged baseline**
Released 9 Sept · Change 1 Delivered [Open](#)

Current file wave 2 unchanged baseline · 2 documents

[Find](#)

 **IFU & labelling** 2 documents

eifu-multilingual.pdf

multi-eo-product-label.pdf

Registration [Open](#)

33 of 65 answers · EUDAMED XML needs all 65

Who can open it [Choose who](#)

Only you, so far.

Identification

UDI-DI
E2E-1788933917911580

Basic UDI-DI
E2EBASIC17889339190855

UDI-PI
—

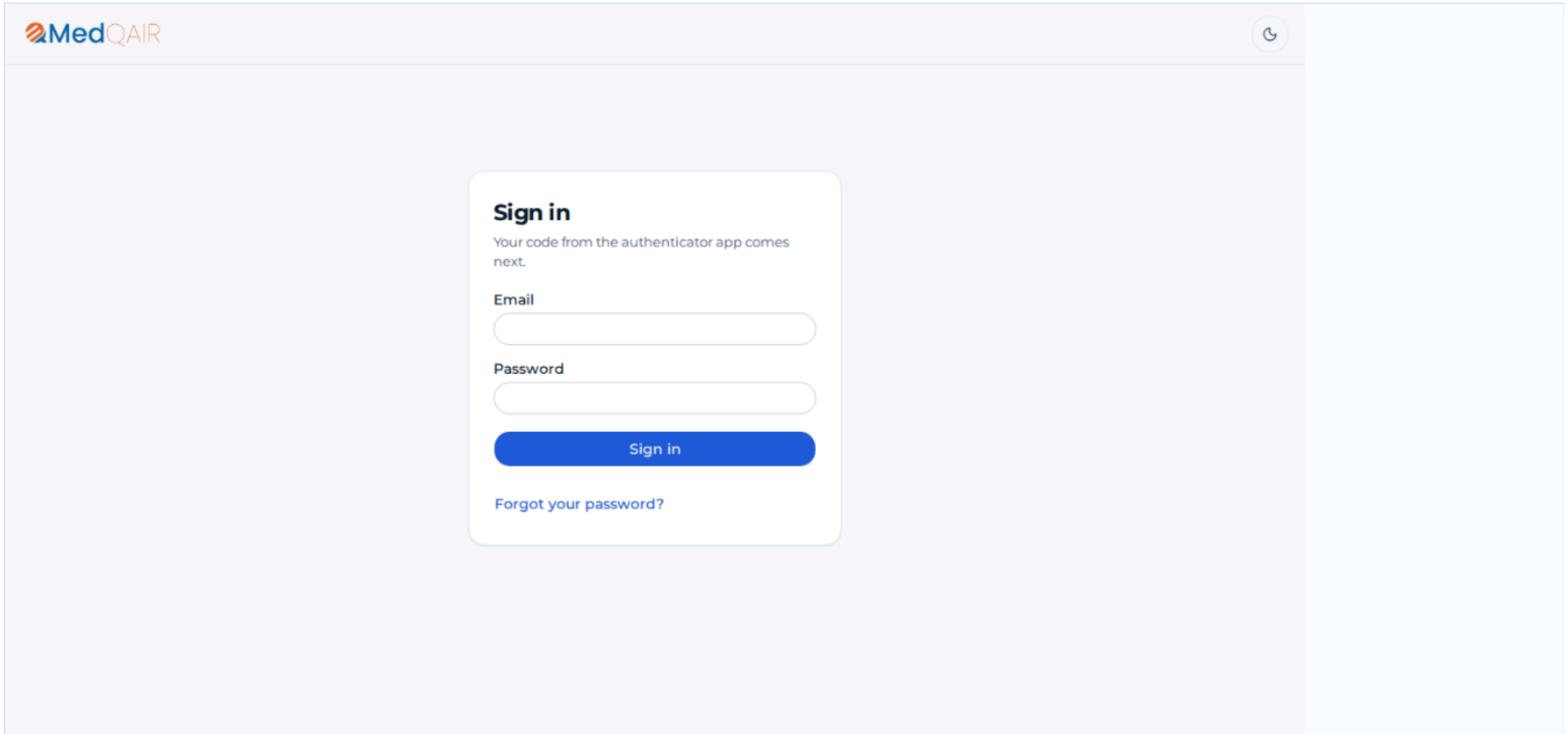
Capture SHA-256: a054f548ac7df877366c6571facb00031d27d567ced9e89301c093ee57a44a9f

A delivered release exports its sealed verification record

The exported bytes and hash are proved after delivery. Before delivery the current endpoint rejects export, so exportability while decisions accumulate remains an explicit gap.

01

EXECUTED GHERKIN STEP

Given the redesign sign-in page **PASS**

Capture SHA-256: 953d9a1220a1b501a0ede3a87b7d5516c6552f0e0d727f3b59246c01ef255e3b

02

EXECUTED GHERKIN STEP

When I sign in to the redesign as a manufacturer **PASS**

 Technical file 

 **TN** [TEST] Northstar Medical Im...
Manufacturer  **EM**

Your work

[TEST] Northstar Medical Imaging · Wednesday 9 September

 **12**
drafts to finish

 **0**
returned for changes

 **0**
waiting on a partner

 **43**
devices, 8 released

[+ Add a device](#)

Needs you

12 drafts

NS Northstar SonoLite Handheld Ultrasound
1.0 first release

Continue

NV Northstar VitalSync Patient Monitor
1.1 labelling update

Continue

NC Northstar CardioMesh Coronary Stent
1.0 first release

Continue

NL Northstar LumaDerm Phototherapy Lamp
Change 1 · first release

Continue

EJ E2E Journey Device 1788933641806128
Change 1 · 1.0.0 · first release

Continue

EJ E2E Journey Device 1788933703671839
Change 1 · 1.0.0 · first release

Continue

Devices · 43

[All 43 >](#)

PA PulseView AR Validation ...

Unreleased

AA AtlasView AR Verification ...

Unreleased

AA AtlasView AR Validation ...

Unreleased

AI AtlasView Importer Verifi...

Unreleased

AI AtlasView Importer Rejec...

Unreleased

AD AtlasView Distributor Veri...

Unreleased

Capture SHA-256: 8095590cd5022eed9d36c1316220d814f7fa52aa347767b791a6e897e2d9193

03

EXECUTED GHERKIN STEP

And I open the isolated release-ledger device PASS

 Technical file 

  TN [TEST] Northstar Medical Im...  EM

Home > Devices > E2E Release Ledger Synthetic Device

 **E2E Release Ledger Synthetic Device** Released

current 1.0 released 9 Sept · Basic UDI-DI 0950600090045D

Choose who

+ Start a change

Changes and releases

Release history

 **1.0**
Released 9 Sept · FIX-REL-CLEAN registered baseline

Delivered Open

Current file 1.0 · 1 document

Find

 **Certificates & declarations**

1 document

Declaration of Conformity · en

approved-baseline

Registration

Open

All 65 answers · ready for EUDAMED XML

Who can open it

Choose who

 **E2E Authorised Rep Co**
Nothing yet · Authorised representative

 **[TEST] Harborline Importers**
All documents

 **[TEST] Sectra Distribution**
All documents

Identification

UDI-DI
09506000900445

Capture SHA-256: 64862196cc07a402f82391bebaa2a17d15add0f622ada51f1505dd5670d4abb8

04

EXECUTED GHERKIN STEP

And I start production version "wave 2 verification record export" PASS

 Technical file 

 TN [TEST] Northstar Medical Im...  EM

Home > E2E Release Ledger Synthetic Device > Change 6

Discard draft

Release

ER

Change 6 Draft

Version wave 2 verification record export follows 1.0 released 9 Sept [Rename](#)

 **Documents** 1

 Add files

 Drop PDFs here · section guessed from the filename, you confirm

1 unchanged documents [Show all](#)

Ready to release? Ready

 **Every upload has a section.**
Settings / Review policy · Documents

 **Your representation for this market is confirmed.**
Who receives it · Release authority & reviewers

 **Waiting for one approval after release**
E2E Authorised Rep Co · approval is required before delivery

 **Registration** Checking...

Loading registration...

[Open registration](#)

Who receives it Choose who

Capture SHA-256: 97c22e5fae963a2851938a777963a527c5c0b867218510a6ab8afd74de17a35a

05

EXECUTED GHERKIN STEP

And I ensure the current release has two documents PASS

 **Technical file** 

 **TN** **[TEST] Northstar Medical Im...**  **EM**

Home › E2E Release Ledger Synthetic Device › Change 6

Change 6 Draft

Version wave 2 verification record export follows 1.0 released 9 Sept [Rename](#)

 **Documents** 3 · 2 changed [Add files](#)

 **Drop PDFs here** · section guessed from the filename, you confirm

 **IFU & labelling** 2 documents

☐ **eifu-multilingual.pdf**
New  ...

☐ **multi-eo-product-label.pdf**
New  ...

1 unchanged documents [Show all](#)

Ready to release? Ready

 **Every upload has a section.**
Settings / Review policy · Documents

 **Your representation for this market is confirmed.**
Who receives it · Release authority & reviewers

 **Waiting for one approval after release**
E2E Authorised Rep Co · approval is required before delivery

 **Registration** Unchanged

Registration matches the registered record.

[Open registration](#)

Capture SHA-256: 74daaf670b1cf50c11a3c559b0324b179a2b915bdd6ce773e44bc1713e6f8920

06

EXECUTED GHERKIN STEP

Then the verification record is unavailable before delivery PASS*No visible change at this step; asserted through the API read*

 **Technical file** 

 **TN** [TEST] Northstar Medical Im...  **EM**

Home > E2E Release Ledger Synthetic Device > Change 6

 **Change 6** Draft

Version wave 2 verification record export follows 1.0 released 9 Sept Rename

 **Documents** 3 · 2 changed

 Add files

 Drop PDFs here · section guessed from the filename, you confirm

 **IFU & labelling**

2 documents

☐ eifu-multilingual.pdf

New

 ...

☐ multi-eo-product-label.pdf

New

 ...

1 unchanged documents Show all

Ready to release? Ready

 **Every upload has a section.**
Settings / Review policy · Documents

 **Your representation for this market is confirmed.**
Who receives it · Release authority & reviewers

 **Waiting for one approval after release**
E2E Authorised Rep Co · approval is required before delivery

 **Registration** Unchanged

Registration matches the registered record.

Open registration

Capture SHA-256: 74daaf670b1cf50c11a3c559b0324b179a2b915bdd6ce773e44bc1713e6f8920

07

EXECUTED GHERKIN STEP

When I clear any carried blocking approvers PASS

 Technical file ▼

 TN [TEST] Northstar Medical Im...
Manufacturer ▼ EM

Who receives it Choose who

TH [TEST] Harborline Importers
Importer · Certificates & declarations · 1 ...

TS [TEST] Sectra Distribution
Distributor · Certificates & declarations · ...

Approvals, in order At once In order

EA **E2E Authorised Rep Co**
Authorised Representative

None Review Approve

TH [TEST] Harborline Importers
Importer

None Review Approve

TS [TEST] Sectra Distribution
Distributor

None Review Approve

EM **E2E Manufacturer**
In your organisation

None Review Approve

Capture SHA-256: dc7d0abb1dd7f047f9f89a74225621e24685577ce47b88cb732a8be998b56284

08

EXECUTED GHERKIN STEP

And I complete and confirm the current release authority **PASS***No visible change at this step; release authority was already confirmed*

 **Technical file** ▼

 **TN** [TEST] Northstar Medical Im...
Manufacturer 

Who receives it Choose who

TH [TEST] Harborline Importers
Importer · Certificates & declarations · 1 ...

TS [TEST] Sectra Distribution
Distributor · Certificates & declarations · ...

Approvals, in order **At once** In order

EA E2E Authorised Rep Co
Authorised Representative

None Review Approve

TH [TEST] Harborline Importers
Importer

None Review Approve

TS [TEST] Sectra Distribution
Distributor

None Review Approve

EM E2E Manufacturer
In your organisation

None Review Approve

Capture SHA-256: dc7d0abb1dd7f047f9f89a74225621e24685577ce47b88cb732a8be998b56284

MDIS walkthrough · 389 / 418

09

EXECUTED GHERKIN STEP

And I press Release once **PASS**

 Technical file 

  [TEST] Northstar Medical Im...  

Home > E2E Release Ledger Synthetic Device > Change 6

 **Change 6** Draft

Version wave 2 verification record export follows 1.0 released 9 Sept Rename

 **Documents** 3 · 2 changed ↑ Add files

 Drop PDFs here · section guessed from the filename, you confirm

 **IFU & labelling** 2 documents

☐ eifu-multilingual.pdf  ...
New

☐ multi-eo-product-label.pdf  ...
New

1 unchanged documents Show all

Ready to release? Ready

 **Every upload has a section.**
Settings / Review policy · Documents

 **Your representation for this market is confirmed.**
Who receives it · Release authority & reviewers

 **Registration** Unchanged
Registration matches the registered record.
Open registration

Who receives it Choose who

 **[TEST] Harborline Importers**
Importer · Certificates & declarations · 1 ...

Capture SHA-256: 55de46ee03e8eee1f91cd61eebe3725fb8ea7f2bba112f92954e872c6387ca99

10

EXECUTED GHERKIN STEP

Then the release is delivered immediately **PASS**

 **Technical file** 

  **[TEST] Northstar Medical Im...**  

Home › E2E Release Ledger Synthetic Device › Change 6

Delivered to the frozen recipient set

 **Change 6** **Delivered**
Version wave 2 verification record export on the market since 9 Sept

 **Documents** 3 · 2 changed · frozen as released

 **IFU & labelling** 2 documents

 eifu-multilingual.pdf
New

 ...

 multi-eo-product-label.pdf
New

 ...

1 unchanged documents [Show all](#)

 **Registration** **Unchanged**
Registration matches the registered record.
[Open registration](#)

Who receives it Choose who

 **[TEST] Sectra Distribution**
Distributor · Certificates & declarations · ...

 **[TEST] Harborline Importers**
Importer · Certificates & declarations · 1 ...

 **Delivery**
Delivered on 2026-09-09.

Summary

Capture SHA-256: 9fae8b71b3624e0c4a2c383f69ee7e76b601146e8d50a3129f0f25a6fd7b3864

11

EXECUTED GHERKIN STEP

When I open the delivered verification record view **PASS**

 Technical file 

 **TN** [TEST] Northstar Medical Im...  **EM**

[Home](#) › [E2E Release Ledger Synthetic Device](#) › [Change 6](#) › [Feedback](#) **Feedback on Change 6** Delivered

Open a finding at the spot it was raised and answer it there.

[Back to the change](#)**Findings, at the spot they were raised**

Declaration of Conformity · approved-baseline

eifu-multilingual.pdf

multi-eo-product-label.pdf

PDF review Exact revision 

Northstar Medical Imaging sample Instructions for Use

Per-document decisions

Decisions are your reviewer's — the threads are yours to answer.

Declaration of Conformity approved-baseline

Awaiting decision

multi-eo-product-label.pdf rev 1

Awaiting decision

eifu-multilingual.pdf rev 1

Awaiting decision

Verification record

builds as decisions land · sealed at release



Capture SHA-256: 2a5eefb88b83bd3b4689bc19956b9ba1000a56fbd2cd510e976f168d6ee1b890

12

EXECUTED GHERKIN STEP

Then the delivered release exports its exact sealed verification record **PASS**

The screenshot shows the MedQAIR interface for 'Technical file'. The breadcrumb trail is 'Home > E2E Release Ledger Synthetic Device > Change 6 > Feedback'. The main heading is 'Feedback on Change 6' with a 'Delivered' status. Below this, there's a section 'Findings, at the spot they were raised' with a table of findings. The table has columns for 'Declaration of Conformity - approved-baseline', 'eifu-multilingual.pdf', and 'multi-eo-product-label.pdf'. There's a 'PDF review' section with 'Exact revision' and a 'Download' button. The 'Per-document decisions' section lists three documents: 'Declaration of Conformity approved-baseline', 'multi-eo-product-label.pdf rev 1', and 'eifu-multilingual.pdf rev 1', each with an 'Awaiting decision' status. The 'Verification record' section states 'builds as decisions land - sealed at release'. A notification at the bottom says 'Sealed verification record downloaded.'

Capture SHA-256: af394cbf9da78a7cfd352853caa209a708dfc34c46d47e413a5403c2c8f0e3bd

features/access-connections/sharing-section-selection.feature · @SR-031 @UR-005 @RSK-001 @RSK-016 @MODULE:ACCESS-CONNECTIONS @SHARING-SECTION-SELECTION

PASS

Section selection composes and removes exact revision pairs without losing another section

This proves saved section/document revision selections on a draft. It does not prove standing live access rules or post-delivery access changes; the broader sharing screen promise remains

partial.

01

EXECUTED GHERKIN STEP

When I include the sharing-selection section "IFU & labelling" PASS

 Technical file 

  [TEST] Northstar Medical Im...  

Home > E2E Journey Device 1788933579021643 > Change 1 > Who receives it

 **Who receives Change 1**
Tick who can open each document after release.

Documents 3 documents

 IFU & labelling 2 documents

Sharing quick guide.pdf

Sharing safety notice.pdf

 Certificates & declarations 1 document

Sharing declaration.pdf

 E2E Authorised Rep Co
2 of 3

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New documents start with nobody. A section tick ticks every row in it; a dimmed tick means some rows are ticked.

What each partner gets

 E2E Authorised Rep Co
Authorised representative - s...

Share

Choose a company... 

+ Add to this device

Invite a new company

Adding a company does not share anything yet — you choose what they can open next.

Access trail

Nothing recorded yet.

Capture SHA-256: b7b68ef0c5eb72373ab28fb31da28c74f4604d5e6132c8bf6bf10c63421d4568

MDIS walkthrough · 394 / 418

02

EXECUTED GHERKIN STEP

And I save the sharing-selection grid PASS

 Technical file 

  [TEST] Northstar Medical Im...  

Home > E2E Journey Device 1788933579021643 > Change 1 > Who receives it



Who receives Change 1

Tick who can open each document after release.

Documents 3 documents

 IFU & labelling 2 documents

Sharing quick guide.pdf

Sharing safety notice.pdf

 Certificates & declarations 1 document

Sharing declaration.pdf

EA

E2E Authorised Rep
Co
2 of 3

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New documents start with nobody. A section tick ticks every row in it; a dimmed tick means some rows are ticked.

What each partner gets

EA

E2E Authorised Rep...
Authorised representa...

Edit access

Choose a company...



+ Add to this device

Invite a new company

Adding a company does not share anything yet — you choose what they can open next.

Access trail

Nothing recorded yet.

Capture SHA-256: e995c92822d5b38825dc845df0632158dee21e2b2d0ae942fd6edfa8608dbf5e

03

EXECUTED GHERKIN STEP

Then the saved sharing selection is exactly "instructions" PASS*No visible change at this step; asserted through the API read*

 **Technical file** 

 TN **[TEST] Northstar Medical Im...**  EM

Home > E2E Journey Device 1788933579021643 > Change 1 > Who receives it

 **Who receives Change 1**
Tick who can open each document after release.

Documents 3 documents

 **IFU & labelling** 2 documents

Sharing quick guide.pdf

Sharing safety notice.pdf

 **Certificates & declarations** 1 document

Sharing declaration.pdf

New documents start with nobody. A section tick ticks every row in it; a dimmed tick means some rows are ticked.

EA

E2E Authorised Rep
Co
2 of 3

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What each partner gets

EA

E2E Authorised Rep...

Authorised representa...

Edit access

Choose a company...

+ Add to this device

Invite a new company

Adding a company does not share anything yet — you choose what they can open next.

Access trail

Nothing recorded yet.

Capture SHA-256: e995c92822d5b38825dc845df0632158dee21e2b2d0ae942fd6edfa8608dbf5e

MDIS walkthrough · 396 / 418

04

EXECUTED GHERKIN STEP

When I include the sharing-selection section "Certificates & declarations" PASS

 Technical file 

  [TEST] Northstar Medical Im...  

Home > E2E Journey Device 1788933579021643 > Change 1 > Who receives it



Who receives Change 1

Tick who can open each document after release.

Back to the change

Save selection

Documents	3 documents	EA E2E Authorised Rep Co all 3
 IFU & labelling	2 documents	☒
Sharing quick guide.pdf		☒
Sharing safety notice.pdf		☒
 Certificates & declarations	1 document	☒
Sharing declaration.pdf		☒

New documents start with nobody. A section tick ticks every row in it; a dimmed tick means some rows are ticked.

What each partner gets

EA

E2E Authorised Rep...

Edit access

Choose a company... 

+ Add to this device

Invite a new company

Adding a company does not share anything yet — you choose what they can open next.

Access trail

Nothing recorded yet.

Capture SHA-256: a24f52564b3abe815824f4749e392209006295459ab9864095f9a23079de924d

05

EXECUTED GHERKIN STEP

And I save the sharing-selection grid **PASS**

 Technical file 

  [TEST] Northstar Medical Im...  
Manufacturer

Home > E2E Journey Device 1788933579021643 > Change 1 > Who receives it

 **Who receives Change 1**
Tick who can open each document after release.

Back to the change

Save selection

Documents 3 documents

 IFU & labelling 2 documents

 Certificates & declarations 1 document

Sharing quick guide.pdf

Sharing safety notice.pdf

Sharing declaration.pdf

EA

E2E Authorised Rep
Co
all 3

☒

☒

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☒

New documents start with nobody. A section tick ticks every row in it; a dimmed tick means some rows are ticked.

What each partner gets

EA

E2E Authorised Rep...
Authorised representa...

Edit access

Choose a company... 

+ Add to this device

Invite a new company

Adding a company does not share anything yet — you choose what they can open next.

Access trail

Nothing recorded yet.

Capture SHA-256: ed4f48e6c6ba58a3dd3691906e5821af5e87e7d7074d1f4dd7d7d348dc3195bd

06

EXECUTED GHERKIN STEP

Then the saved sharing selection is exactly "all" PASS*No visible change at this step; asserted through the API read*

 **Technical file** 

  **[TEST] Northstar Medical Im...**  

Home > E2E Journey Device 1788933579021643 > Change 1 > Who receives it

 **Who receives Change 1**
Tick who can open each document after release.

Documents 3 documents

 **IFU & labelling** 2 documents

Sharing quick guide.pdf

Sharing safety notice.pdf

 **Certificates & declarations** 1 document

Sharing declaration.pdf

New documents start with nobody. A section tick ticks every row in it; a dimmed tick means some rows are ticked.

 **E2E Authorised Rep Co**
all 3











What each partner gets

 **E2E Authorised Rep...**
Authorised representa...

Edit access

Choose a company...



+ Add to this device

Invite a new company

Adding a company does not share anything yet — you choose what they can open next.

Access trail

Nothing recorded yet.

Capture SHA-256: ed4f48e6c6ba58a3dd3691906e5821af5e87e7d7074d1f4dd7d7d348dc3195bd

07

EXECUTED GHERKIN STEP

When I exclude the sharing-selection section "IFU & labelling" PASS

 Technical file 

  [TEST] Northstar Medical Im...  

Home > E2E Journey Device 1788933579021643 > Change 1 > Who receives it



Who receives Change 1

Tick who can open each document after release.

Documents 3 documents

 IFU & labelling 2 documents

Sharing quick guide.pdf

Sharing safety notice.pdf

 Certificates & declarations 1 document

Sharing declaration.pdf

 E2E Authorised Rep Co
1 of 3

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New documents start with nobody. A section tick ticks every row in it; a dimmed tick means some rows are ticked.

What each partner gets

 E2E Authorised Rep...
Authorised representa...

Edit access

Choose a company... 

+ Add to this device

Invite a new company

Adding a company does not share anything yet — you choose what they can open next.

Access trail

Nothing recorded yet.

Capture SHA-256: bc14ecbc4b9508882b0aa0635cb9e83b0bc7ae48d249c2384c8bf97afbea4a39

08

EXECUTED GHERKIN STEP

And I save the sharing-selection grid PASS

 Technical file 

  [TEST] Northstar Medical Im...  
Manufacturer

Home > E2E Journey Device 1788933579021643 > Change 1 > Who receives it

 **Who receives Change 1**
Tick who can open each document after release.

Back to the change

Save selection

Documents 3 documents

 IFU & labelling 2 documents

Sharing quick guide.pdf

Sharing safety notice.pdf

 Certificates & declarations 1 document

Sharing declaration.pdf

 E2E Authorised Rep Co
1 of 3

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What each partner gets

 E2E Authorised Rep...
Authorised representa...

Edit access

Choose a company... 

+ Add to this device

Invite a new company

Adding a company does not share anything yet — you choose what they can open next.

Access trail

Nothing recorded yet.

New documents start with nobody. A section tick ticks every row in it; a dimmed tick means some rows are ticked.

Capture SHA-256: f2d8fecc028c76f7a5f671b19828318efedd77f106dc8a4c50c7ee702bdd693

09

EXECUTED GHERKIN STEP

Then the saved sharing selection is exactly "declaration" PASS*No visible change at this step; asserted through the API read*

The screenshot displays the MedQAIR 'Technical file' interface. The breadcrumb trail is 'Home > E2E Journey Device 1788933579021643 > Change 1 > Who receives it'. The main heading is 'Who receives Change 1' with a subtext 'Tick who can open each document after release.' On the right, there are buttons for 'Back to the change' and 'Save selection'. The interface is divided into two main sections: 'Documents' and 'What each partner gets'.

Documents 3 documents

Document	E2E Authorised Rep Co 1 of 3
IFU & labelling 2 documents	☐
Sharing quick guide.pdf	☐
Sharing safety notice.pdf	☐
Certificates & declarations 1 document	☒
Sharing declaration.pdf	☒

New documents start with nobody. A section tick ticks every row in it; a dimmed tick means some rows are ticked.

What each partner gets

E2E Authorised Rep... Edit access
Authorised representa...

Choose a company...

+ Add to this device

Invite a new company

Adding a company does not share anything yet — you choose what they can open next.

Access trail

Nothing recorded yet.

Capture SHA-256: f2d8fecc028c76f7a5f671b19828318efedd77f106dc8a4c50c7ee702bdd693

10

EXECUTED GHERKIN STEP

When I reload the run-owned sharing-selection grid PASS

 Technical file 

  [TEST] Northstar Medical Im...  

Home > E2E Journey Device 1788933579021643 > Change 1 > Who receives it



Who receives Change 1

Tick who can open each document after release.

[Back to the change](#) [Save selection](#)

Documents 3 documents

 IFU & labelling 2 documents

Sharing quick guide.pdf

Sharing safety notice.pdf

 Certificates & declarations 1 document

Sharing declaration.pdf

 E2E Authorised Rep Co
1 of 3

☐

☐

☐

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What each partner gets

 E2E Authorised Rep...
Authorised representa...

Edit access

Choose a company... 

[+ Add to this device](#)

[Invite a new company](#)

Adding a company does not share anything yet — you choose what they can open next.

Access trail

Nothing recorded yet.

New documents start with nobody. A section tick ticks every row in it; a dimmed tick means some rows are ticked.

Capture SHA-256: fe1535744d12153e03450106af9a85a70109f52262deb5aa15465b87990516f1

11 EXECUTED GHERKIN STEP

Then the saved sharing selection is exactly "declaration" PASS

No visible change at this step; asserted through the API read

MedQAIR

Technical file

TN

[TEST] Northstar Medical Im...
Manufacturer

EM

Home > E2E Journey Device 1788933579021643 > Change 1 > Who receives it

Who receives Change 1

Tick who can open each document after release.

Documents3 documents

IFU & labelling2 documents

Sharing quick guide.pdf

Sharing safety notice.pdf

Certificates & declarations1 document

Sharing declaration.pdf

New documents start with nobody. A section tick ticks every row in it; a dimmed tick means some rows are ticked.

EA

E2E Authorised Rep
Co
1 of 3

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What each partner gets

EA

E2E Authorised Rep...
Authorised representa...

Edit access

Choose a company...

+ Add to this device

Invite a new company

Adding a company does not share anything yet — you choose what they can open next.

Access trail

Nothing recorded yet.

Capture SHA-256: fe1535744d12153e03450106af9a85a70109f52262deb5aa15465b87990516f1

features/access-connections/sharing-section-selection.feature · @SR-031 @UR-005 @RSK-001 @RSK-016 @MODULE:ACCESS-CONNECTIONS @SHARING-SECTION-SELECTION

PASS

A mixed section can become an explicitly empty saved audience

This proves saved section/document revision selections on a draft. It does not prove standing live access rules or post-delivery access changes; the broader sharing screen promise remains

MDIS walkthrough · 404 / 418

partial.

01

EXECUTED GHERKIN STEP

When I include the sharing-selection section "IFU & labelling" **PASS**

Technical file

[TEST] Northstar Medical Im...
Manufacturer

Home > E2E Journey Device 1788933587668687 > Change 1 > Who receives it

Who receives Change 1

Tick who can open each document after release.

Back to the change
Save selection

EA

E2E Authorised Rep Co

2 of 3

Documents 3 documents	
IFU & labelling 2 documents	☒
Sharing quick guide.pdf	☒
Sharing safety notice.pdf	☒
Certificates & declarations 1 document	☐
Sharing declaration.pdf	☐

New documents start with nobody. A section tick ticks every row in it; a dimmed tick means some rows are ticked.

What each partner gets

EA

E2E Authorised Rep Co

Authorised representative - s...

Share

Choose a company...

+ Add to this device

Invite a new company

Adding a company does not share anything yet — you choose what they can open next.

Access trail

Nothing recorded yet.

Capture SHA-256: c8c037f1c1ab9258a6c45bcb0db6178cb286418674e889ac916782fe16c5222e

02

EXECUTED GHERKIN STEP

And I save the sharing-selection grid PASS

 Technical file 

  [TEST] Northstar Medical Im...  

Home > E2E Journey Device 1788933587668687 > Change 1 > Who receives it



Who receives Change 1

Tick who can open each document after release.

Documents 3 documents

 IFU & labelling 2 documents

Sharing quick guide.pdf

Sharing safety notice.pdf

 Certificates & declarations 1 document

Sharing declaration.pdf

 E2E Authorised Rep Co
2 of 3

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New documents start with nobody. A section tick ticks every row in it; a dimmed tick means some rows are ticked.

What each partner gets

 E2E Authorised Rep...
Authorised representa...

Edit access

Choose a company... 

+ Add to this device

Invite a new company

Adding a company does not share anything yet — you choose what they can open next.

Access trail

Nothing recorded yet.

Capture SHA-256: 2849c3e4cb59803c20ba412bfab4c421fa61f7d3e678fbb9f72dcb4219e12319

03

EXECUTED GHERKIN STEP

Then the saved sharing selection is exactly "instructions" PASS*No visible change at this step; asserted through the API read*

 **Technical file** 

  [TEST] Northstar Medical Im...  

[Home](#) > [E2E Journey Device 1788933587668687](#) > [Change 1](#) > Who receives it



Who receives Change 1

Tick who can open each document after release.

Documents 3 documents

 **IFU & labelling** 2 documents

Sharing quick guide.pdf

Sharing safety notice.pdf

 **Certificates & declarations** 1 document

Sharing declaration.pdf

New documents start with nobody. A section tick ticks every row in it; a dimmed tick means some rows are ticked.

 **E2E Authorised Rep Co**
2 of 3

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What each partner gets

 **E2E Authorised Rep...**
Authorised representa...

Edit access

Choose a company...



+ Add to this device

Invite a new company

Adding a company does not share anything yet — you choose what they can open next.

Access trail

Nothing recorded yet.

Capture SHA-256: 2849c3e4cb59803c20ba412bfab4c421fa61f7d3e678fbb9f72dcb4219e12319

04

EXECUTED GHERKIN STEP

When I exclude the sharing-selection safety notice PASS

 Technical file 

  [TEST] Northstar Medical Im...  

Home > E2E Journey Device 1788933587668687 > Change 1 > Who receives it



Who receives Change 1

Tick who can open each document after release.

Documents 3 documents

 IFU & labelling 2 documents

Sharing quick guide.pdf

Sharing safety notice.pdf

 Certificates & declarations 1 document

Sharing declaration.pdf

 E2E Authorised Rep Co
1 of 3

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What each partner gets

 E2E Authorised Rep...
Authorised representa...

Edit access

Choose a company... 

+ Add to this device

Invite a new company

Adding a company does not share anything yet — you choose what they can open next.

Access trail

Nothing recorded yet.

Capture SHA-256: d49899e6de9d7e87eed310771642c23023a581d5ca0c5cb69d1c92931851f8c

EXECUTED GHERKIN STEP

Then the sharing-selection instructions section visibly has a mixed selection PASS

No visible change at this step; the mixed section and its individual document selections remain visible

MedQAIR

Technical file

↺

TN [TEST] Northstar Medical Im...
Manufacturer

EM

Home > E2E Journey Device 1788933587668687 > Change 1 > Who receives it

Who receives Change 1

Tick who can open each document after release.

Documents 3 documents

IFU & labelling 2 documents

Sharing quick guide.pdf

Sharing safety notice.pdf

Certificates & declarations 1 document

Sharing declaration.pdf

E2E Authorised Rep Co
1 of 3

EA

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New documents start with nobody. A section tick ticks every row in it; a dimmed tick means some rows are ticked.

What each partner gets

E2E Authorised Rep...
Authorised representa...

Edit access

Choose a company...

+ Add to this device

Invite a new company

Adding a company does not share anything yet — you choose what they can open next.

Access trail

Nothing recorded yet.

Capture SHA-256: d49899e6de9d7e87eefd310771642c23023a581d5ca0c5cb69d1c92931851f8c

06

EXECUTED GHERKIN STEP

When I save the sharing-selection grid PASS

 Technical file 

  [TEST] Northstar Medical Im...  

Home > E2E Journey Device 1788933587668687 > Change 1 > Who receives it



Who receives Change 1

Tick who can open each document after release.

Documents 3 documents

 IFU & labelling 2 documents

Sharing quick guide.pdf

Sharing safety notice.pdf

 Certificates & declarations 1 document

Sharing declaration.pdf

 E2E Authorised Rep Co
1 of 3

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New documents start with nobody. A section tick ticks every row in it; a dimmed tick means some rows are ticked.

What each partner gets

 E2E Authorised Rep...
Authorised representa...

Edit access

Choose a company... 

+ Add to this device

Invite a new company

Adding a company does not share anything yet — you choose what they can open next.

Access trail

Nothing recorded yet.

Capture SHA-256: 8c14b262791349e73d43d96cd7cd70c228a29bc90863ddb8186030bef0bd737

07

EXECUTED GHERKIN STEP

Then the saved sharing selection is exactly "quick guide" PASS*No visible change at this step; asserted through the API read*

 Technical file 

 TN [TEST] Northstar Medical Im...  EM

Home > E2E Journey Device 1788933587668687 > Change 1 > Who receives it

 **Who receives Change 1**
Tick who can open each document after release.

Documents 3 documents

 IFU & labelling 2 documents

Sharing quick guide.pdf

Sharing safety notice.pdf

 Certificates & declarations 1 document

Sharing declaration.pdf

EA

E2E Authorised Rep
Co
1 of 3











New documents start with nobody. A section tick ticks every row in it; a dimmed tick means some rows are ticked.

Back to the change

Save selection

What each partner gets

EA

E2E Authorised Rep...

Authorised representa...

Edit access

Choose a company...



+ Add to this device

Invite a new company

Adding a company does not share anything yet — you choose what they can open next.

Access trail

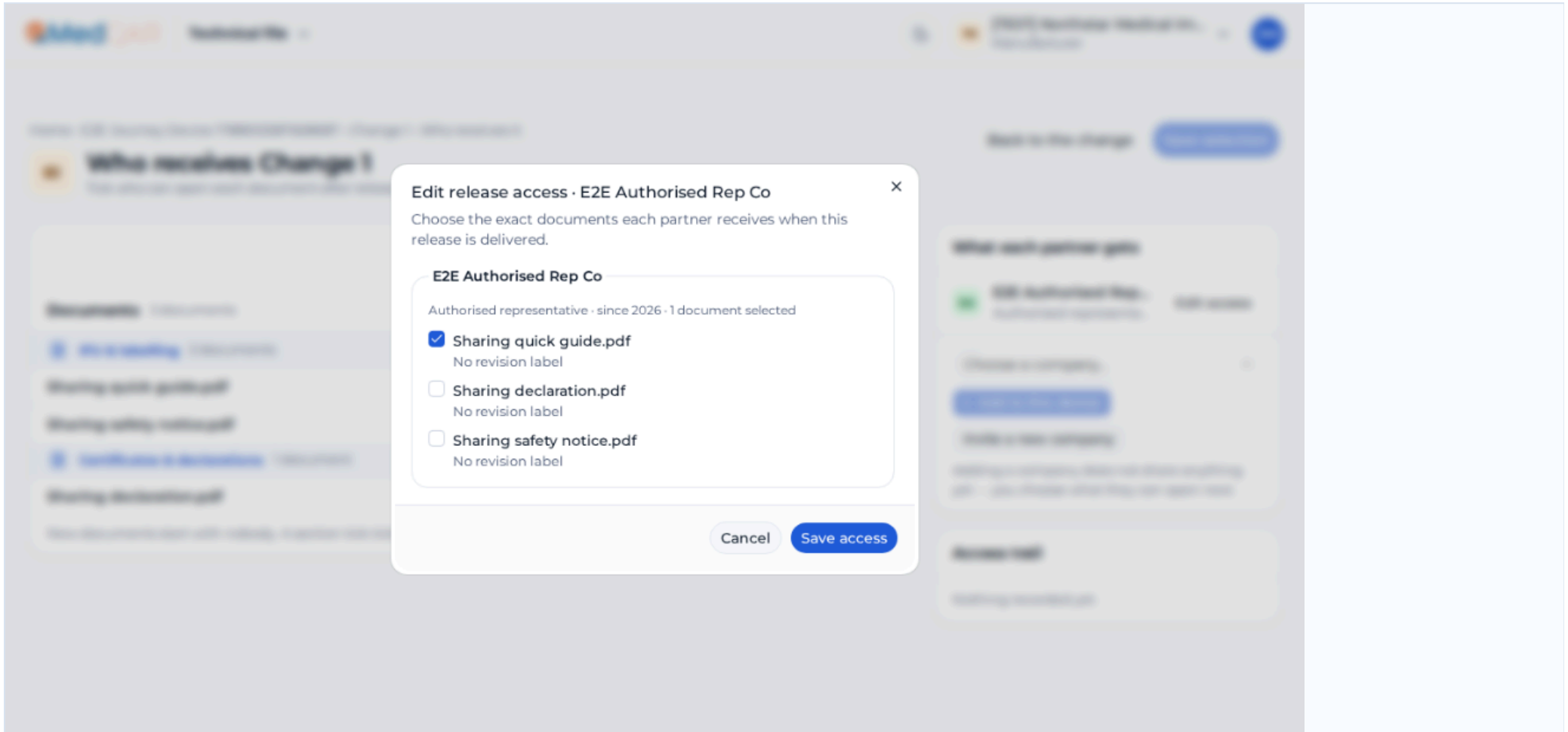
Nothing recorded yet.

Capture SHA-256: 8c14b262791349e73d43d96cd7cd70c228a29bc90863ddb8186030bef0bd737

MDIS walkthrough · 411 / 418

08

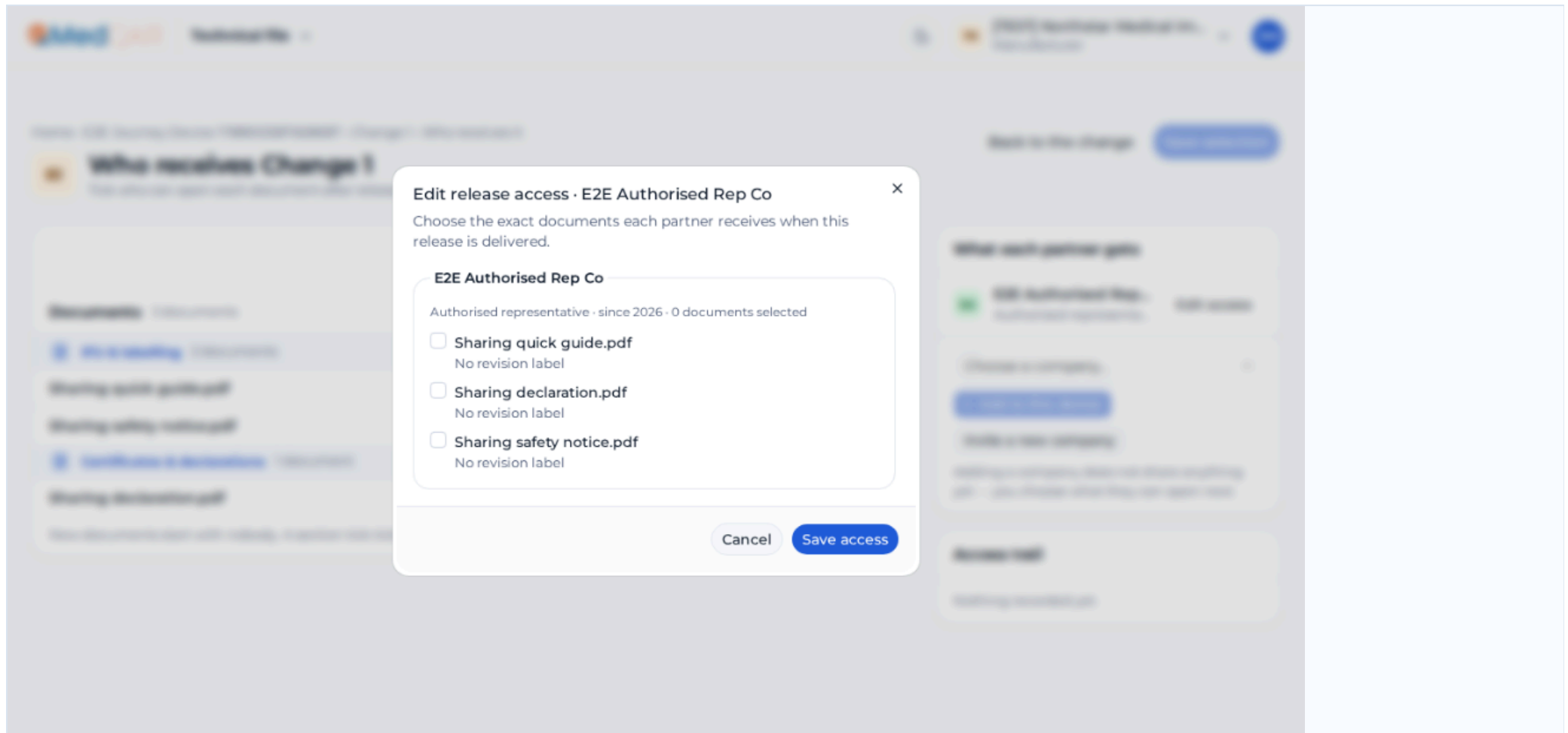
EXECUTED GHERKIN STEP

When I open the sharing-selection partner's Edit access dialog PASS

Capture SHA-256: 4ff594d1a5aa98c00a7995639e302797a5a1bd8a5567fd9c4a8889e505790334

09

EXECUTED GHERKIN STEP

And I clear the last sharing-selection document in the dialog PASS

Capture SHA-256: 1c0fce32320a79917c2972d5b502a4ff8cbfa22f52a3f4e7a2a34b0a402f5efc

10

EXECUTED GHERKIN STEP

And I save the empty sharing-selection dialog **PASS**

 Technical file 

  [TEST] Northstar Medical Im...  

Home > E2E Journey Device 1788933587668687 > Change 1 > Who receives it

 **Who receives Change 1**
Tick who can open each document after release.

Back to the change

Save selection

Documents 3 documents

 IFU & labelling 2 documents

Sharing quick guide.pdf

Sharing safety notice.pdf

 Certificates & declarations 1 document

Sharing declaration.pdf

 E2E Authorised Rep Co
0 of 3

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What each partner gets

 E2E Authorised Rep Co
Authorised representative · s...

Share

Choose a company...



+ Add to this device

Invite a new company

Adding a company does not share anything yet — you choose what they can open next.

Access trail

Nothing recorded yet.

New documents start with nobody. A section tick ticks every row in it; a dimmed tick means some rows are ticked.

Capture SHA-256: 817d8149c81ee3b84c8a71186d766f9f622f76fbe5ab8150c4b71d461c67d535

11

EXECUTED GHERKIN STEP

Then the saved sharing selection is exactly "none" PASS*No visible change at this step; asserted through the API read*

 **Technical file** 

  **[TEST] Northstar Medical Im...**  

Home > E2E Journey Device 1788933587668687 > Change 1 > Who receives it

 **Who receives Change 1**
Tick who can open each document after release.

Documents 3 documents

 **IFU & labelling** 2 documents

Sharing quick guide.pdf

Sharing safety notice.pdf

 **Certificates & declarations** 1 document

Sharing declaration.pdf

New documents start with nobody. A section tick ticks every row in it; a dimmed tick means some rows are ticked.

**E2E Authorised Rep Co**
0 of 3

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What each partner gets

**E2E Authorised Rep Co**
Authorised representative · s...

Share

Choose a company... 

+ Add to this device

Invite a new company

Adding a company does not share anything yet — you choose what they can open next.

Access trail

Nothing recorded yet.

Capture SHA-256: 817d8149c81ee3b84c8a71186d766f9f622f76fbe5ab8150c4b71d461c67d535

12

EXECUTED GHERKIN STEP

When I reload the run-owned sharing-selection grid PASS

 **Technical file** 

  **[TEST] Northstar Medical Im...**  

Home > E2E Journey Device 1788933587668687 > Change 1 > Who receives it

 **Who receives Change 1**
Tick who can open each document after release.

Documents 3 documents

 **IFU & labelling** 2 documents

Sharing quick guide.pdf

Sharing safety notice.pdf

 **Certificates & declarations** 1 document

Sharing declaration.pdf

New documents start with nobody. A section tick ticks every row in it; a dimmed tick means some rows are ticked.

 **E2E Authorised Rep Co**
0 of 3

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What each partner gets

 **E2E Authorised Rep Co**
Authorised representative · s...

Share

Choose a company... 

+ Add to this device

Invite a new company

Adding a company does not share anything yet — you choose what they can open next.

Access trail

Nothing recorded yet.

Capture SHA-256: 5a4f822c5b5b77b9ee2f58d66050faf11008f06ce50afbc1122c5d7363394dc0

EXECUTED GHERKIN STEP

PASS

No visible change at this step; asserted through the API read

MedQAIR

Technical file

🔄

TN [TEST] Northstar Medical Im...
Manufacturer

EM

Home > E2E Journey Device 1788933587668687 > Change 1 > Who receives it

Who receives Change 1

Tick who can open each document after release.

Documents 3 documents

IFU & labelling 2 documents

Sharing quick guide.pdf

Sharing safety notice.pdf

Certificates & declarations 1 document

Sharing declaration.pdf

EA

E2E Authorised Rep Co

0 of 3

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New documents start with nobody. A section tick ticks every row in it; a dimmed tick means some rows are ticked.

What each partner gets

EA E2E Authorised Rep Co

Authorised representative · s...

Share

Choose a company...

+ Add to this device

Invite a new company

Adding a company does not share anything yet — you choose what they can open next.

Access trail

Nothing recorded yet.

Capture SHA-256: 5a4f822c5b5b77b9ee2f58d66050faf11008f06ce50afbc1122c5d7363394dc0

Scope and disposition

Qualified shared run. Representative workflow; no client validation approval

Ledger snapshot: 17 real-stack · 25 preview-only · 41 uncovered · 1 recorded of 84. [Screen ledger source](#)

Requirement register: 9 covered · 12 partial · 3 blocked of 24. [Requirement register source](#)

The two registers count different things: the screen ledger tracks 84 redesign screens and composite interaction promises; the requirement register tracks 24 user requirements. A passing scenario can prove only part of a composite entry, so it does not automatically retire that screen's remaining gaps.

These screenshots show the selected executed workflow and its recorded assertions. They do not constitute broader validation, controlled approval, or a client adoption decision. Authentication links, codes, failure traces, and secret-safe journeys are deliberately excluded from captures.

Client adoption record — unapproved

No client approval is recorded. Complete and approve these decisions in your own controlled validation process, retaining this sealed evidence bundle as supporting material.

CLIENT AND INTENDED USE Not recorded	VERSION AND CONFIGURATION ASSESSED Not recorded
LOCAL RISKS AND ADDITIONAL CHECKS Not recorded	DEVIATIONS AND ACCEPTANCE DECISION Not recorded
VALIDATION OWNER AND REVIEWER Not recorded	APPROVAL AND DATE Unapproved

Retain any separate approved adoption record alongside this bundle. Generating or sharing the walkthrough does not complete these decisions.