

Follow one device dossier from release to correction

Intended use shown

An authorised manufacturer uses MDIS to prepare a device document release, obtain a partner's review, correct an affected document and deliver the approved successor. The worked example is the synthetic **AtlasView Multi-EO Release Monitor** dossier.

The story

39 consecutive steps, 39 original screenshots. Follow the manufacturer, the authorised representative and an unrelated company in separate authenticated sessions. Each page carries the exact executed Gherkin step and its observed outcome.

Disposition

Representative workflow evidence. A passing scenario supports this defined workflow on the recorded candidate. It does not approve every MDIS requirement, every redesign screen, or a client's own configuration.

How to read it

Read the expectation above each image, then compare the observed result with the screen. Assertions about persisted identities, revisions and audit history are identified explicitly: those facts are not established by a screenshot alone. The PDF uses large A3 landscape pages; each page shows the captured viewport; full original images remain available in the HTML; the companion HTML opens offline and supports full-size images.

What was exercised - and where

Software and environment

MDIS **ui-v2 + API + PostgreSQL**, built and run as a local disposable Docker stack. Chromium automated browser execution. Synthetic accounts and documents only. Storage uses fake GCS, email uses Mailpit with the SMTP proxy, and EUDAMED uses the disposable simulator; these external production services are not validated here.

Starting conditions

The disposable seed supplies an existing device dossier and connected operators. This focused story adds an authorised representative, opens its first release candidate and prepares two synthetic document revisions. It begins after account and device provisioning; those setup workflows and medical-device clinical use are outside this story.

Record identity

Run: **local-b275539ea5-20260907T172831Z**

Source: MedQAIR/MDIS @ b275539ea53f70cb04466895853fe05c7fd62c86

Focused story execution: 2026-09-07T17:29:09.104Z to 2026-09-07T17:29:19+00:00 UTC.

The screenshots and source-input hashes are recorded in the accompanying evidence index.

Traceability boundary

The exact scenario is **A visible changes request stops one release and its successor can deliver**, in **features/release-integration/release-document-feedback.feature**, tagged **@SR-197 / @VAL-REL-019**. Its wider UR and risk tags are routing metadata, not evidence that every obligation under those requirements passed.

Introduce the participants

EXPECTED

Three independent sessions represent the manufacturer, its reviewer and an unrelated company.

OBSERVED / STEP PASSED

Three distinct browser contexts and selected context identities were verified.



Technical file

TN

[TEST] Northstar Medical Im...
Manufacturer

EM

Your work

[TEST] Northstar Medical Imaging · Monday 7 September

+ Add a device

4

drafts to finish

0

returned for changes

0

waiting on a partner

21

devices, 4 released

Needs you

4 drafts

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

NC

Northstar CardioMesh Coronary Stent

1.0 first release

Continue

Devices · 21

All 21

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

AD

AtlasView Distributor Veri...

Unreleased

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

Synthetic disposable-stack evidence | b275539ea53f | 7 September 2026

3

Open the device dossier

EXPECTED

Open the existing AtlasView Multi-EO Release Monitor dossier.

OBSERVED / STEP PASSED

The recorded device URL opens in ui-v2; this starts from a seeded dossier.



Technical file

TN

[TEST] Northstar Medical Im...
Manufacturer

EM

Home › Devices › AtlasView Multi-EO Release Monitor

AM

AtlasView Multi-EO Release Monitor

Unreleased

not released yet · Basic UDI-DI 0950600090035B

Changes and releases

No changes yet.

Choose who

+ Start first release

Registration

Open

Not started. EUDAMED needs every answer.

Who can open it

Choose who

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

Identification

And I open the current multi-EO release device

Inspect the device's connections

EXPECTED

Open Who receives it to inspect the device's economic operators.

OBSERVED / STEP PASSED

The current access surface is available for this device.



⌕

EM

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

Back to the device

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.

TH

[TEST] Harborline I...

Importer · since 2020 · ...

0 documents

TS

[TEST] Sectra Distri...

Distributor · since 2020...

0 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 yet — you choose what they can open next.

And I open the device's access page

Connect the authorised representative

EXPECTED

Add the test authorised representative to the device.

OBSERVED / STEP PASSED

The representative is added through the current access surface. A connection alone is not a document grant.





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.

What each partner gets

EA	E2E Authorised Rep Co	Authorised representativ...	Not shared
TH	[TEST] Harborline I...	Importer · since 2020 · ...	0 documents
TS	[TEST] Sectra Distri...	Distributor · since 2020...	0 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 yet

Back to the device

And I add the authorised representative to this device

Return to the device

EXPECTED

Return to the same device before preparing a change.

OBSERVED / STEP PASSED

The browser returns to the recorded device URL.



EM

Home › Devices › AtlasView Multi-EO Release Monitor

AM

AtlasView Multi-EO Release Monitor

Unreleased

not released yet · Basic UDI-DI 0950600090035B

Choose who

+ Start first release

Changes and releases

No changes yet.

Registration

Open

Loading...

Who can open it

Choose who

Loading...

Identification

UDI-DI

09506000901541

Basic UDI-DI

0950600090035B

UDI-PI

—

And I go back to the device

Start the release candidate

EXPECTED

Create the named production-version draft using the current change flow.

OBSERVED / STEP PASSED

A new draft opens for VAL-REL-019 automated review.

 **Technical file** 

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

Home > AtlasView Multi-EO Release Monitor > Change 1

AM

Change 1

Draft

Version VAL-REL-019 automated review

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.**
Documents

 **This market is outside your own country and needs a confirmed authorised representative — confirm it under Economic Operators.**
Release authority & reviewers · recommended, does not hold release

 **Registration** Checking...

Loading registration...

Open registration

Who receives it Choose who

Nobody receives this release.

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

Prepare two document revisions

EXPECTED

The release contains the product label and an unaffected multilingual eIFU.

OBSERVED / STEP PASSED

Two document revisions are available in the candidate. This is seeded test content.



Technical file 



TN

[TEST] Northstar Medical Im...
Manufacturer

EM

Home > AtlasView Multi-EO Release Monitor > Change 1

AM

Change 1

Draft

Version VAL-REL-019 automated review

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.
Documents



This market is outside your own country and needs a confirmed authorised representative — confirm it under Economic Operators.
Release authority & reviewers · recommended, does not hold release



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

And I ensure the current release has two documents

Confirm release authority

EXPECTED

Complete and confirm the current release-authority fields.

OBSERVED / STEP PASSED

The journey completes the release-authority controls before releasing.



Technical file 



TN

[TEST] Northstar Medical Im...
Manufacturer

EM

Home > AtlasView Multi-EO Release Monitor > Change 1

AM

Change 1

Draft

Version VAL-REL-019 automated review

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.

Documents



This market is outside your own country and needs a confirmed authorised representative — confirm it under Economic Operators.

Release authority & reviewers · recommended, does not hold release



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

And I complete and confirm the current release authority

Choose the delivery recipient

EXPECTED

Select the product-label revision for the test importer.

OBSERVED / STEP PASSED

The selection is saved through the UI; a fresh API read contains the target revision.



Technical file 



TN

[TEST] Northstar Medical Im...
Manufacturer

EM

Home > AtlasView Multi-EO Release Monitor > Change 1

AM

Change 1

Draft

Version VAL-REL-019 automated review

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.
Documents



This market is outside your own country and needs a confirmed authorised representative — confirm it under Economic Operators.
Release authority & reviewers · recommended, does not hold release

 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

And I configure the fresh anchored-feedback delivery

Require the representative's approval

EXPECTED

Configure the authorised representative as a blocking approver.

OBSERVED / STEP PASSED

The representative is selected as Approve before the release action.

 **Technical file** 



TN

[TEST] Northstar Medical Im...
Manufacturer



EM

Answer remaining 37

Open registration

Who receives it

Choose who

TH

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

Approvals, in order

At once

In order

EA

E2E Authorised Rep Co
Authorised Representative · Approver

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

And I configure the authorised representative as a blocking approver

Synthetic disposable-stack evidence | b275539ea53f | 7 September 2026

12

Release once

EXPECTED

Submit this candidate once for its configured approval process.

OBSERVED / STEP PASSED

One Release action submits the candidate. The next step checks the waiting state.



Technical file 



TN

[TEST] Northstar Medical Im...
Manufacturer

EM

Home › AtlasView Multi-EO Release Monitor › Change 1

AM

Change 1

Draft

Version VAL-REL-019 automated review [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.

Documents



This market is outside your own country and needs a confirmed authorised representative — confirm it under Economic Operators.

Release authority & reviewers · recommended, does not hold release



Waiting for one approval after release

E2E Authorised Rep Co · approval is required before delivery

 Registration

Incomplete

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

Answer remaining 37

Open registration

And I release this tracked candidate once

Wait for the blocking decision

EXPECTED

Delivery must wait while the blocking approval is outstanding.

OBSERVED / STEP PASSED

The release visibly waits for approval; delivery has not activated.



Technical file 



TN

[TEST] Northstar Medical Im...
Manufacturer

EM

Home › AtlasView Multi-EO Release Monitor › Change 1

AM

Change 1

Waiting

Version VAL-REL-019 automated review follows VAL-REL-019 automated review released 7 Sept

 Documents 2 · 2 changed · frozen as released

 IFU & labelling

2 documents

multi-eo-product-label.pdf

New

 ...

eifu-multilingual.pdf

New

 ...

 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 · o...

Approvals, in order

1

E2E Authorised Rep Co

Approver · Asked now

Now



Delivery to 1 partner

Starts by itself on the last approval

Then delivery is visibly waiting for its blocking decision

Hand over to the reviewer

EXPECTED

Continue in the representative's own authenticated session.

OBSERVED / STEP PASSED

The selected actor, user and context are checked against the representative's retained session.

 **Technical file** 

   **E2E Authorised Rep Co**
Authorised Representative  

Your work

E2E Authorised Rep Co · Monday 7 September

 **3**
releases to approve

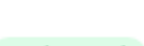
 **8**
devices shared with you

Needs you

	ClearPath Release Monitor Approve the release · Approval requested by [TEST] Northstar Medical Imaging	
	Northstar OxyTrack Pulse Oximeter Approve the release · Approval requested by [TEST] Northstar Medical Imaging	
	Northstar NeuroScan EEG Cap Approve the release · Review requested by [TEST] Northstar Medical Imaging	

Devices · 8

[All 8 ›](#)

	PulseView AR Validation ...	
	AtlasView AR Verification ...	
	AtlasView AR Validation ...	
	AtlasView Multi-EO Relea...	
	ClearPath Release Monitor Candidate 1 released 7 Sept	
	Northstar VitalSync Patient...	

When the authorised representative takes over the anchored-feedback review

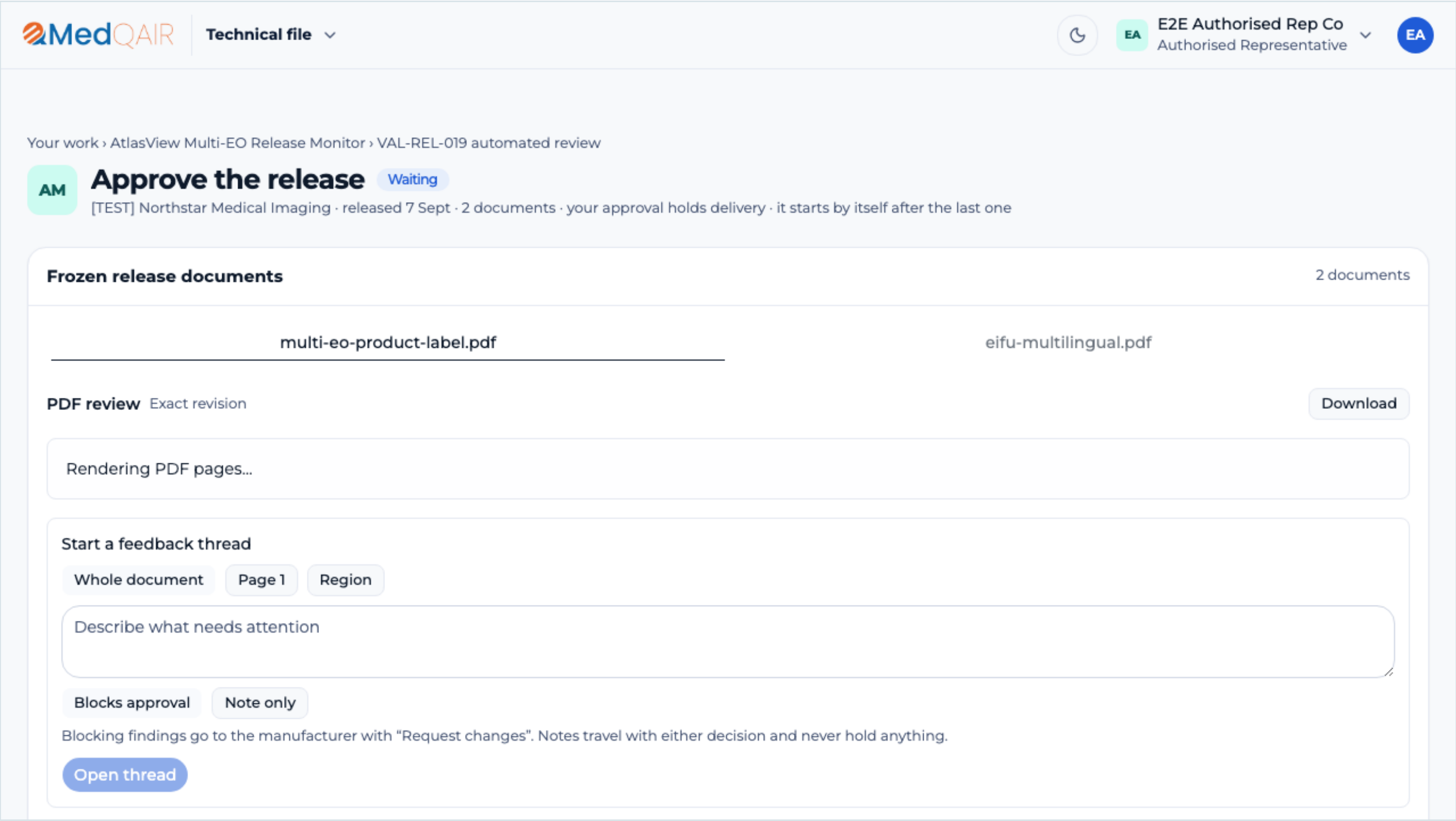
Open the exact approval request

EXPECTED

Open this release's request from the work queue.

OBSERVED / STEP PASSED

The exact tracked release is selected; Approve the release and Frozen release documents are visible.



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

Viewport extract: top 720 pixels of the original screenshot. The full original is embedded in the HTML companion.

Anchor feedback to the PDFs

EXPECTED

Create region feedback on the label and separate page feedback on the unchanged eIFU.

OBSERVED / STEP PASSED

Both anchors were asserted in their respective document tabs; API responses bind each to its exact revision and approver.

 **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

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

And I open anchored feedback on the changed and unaffected PDFs

Viewport extract: top 720 pixels of the original screenshot. The full original is embedded in the HTML companion.

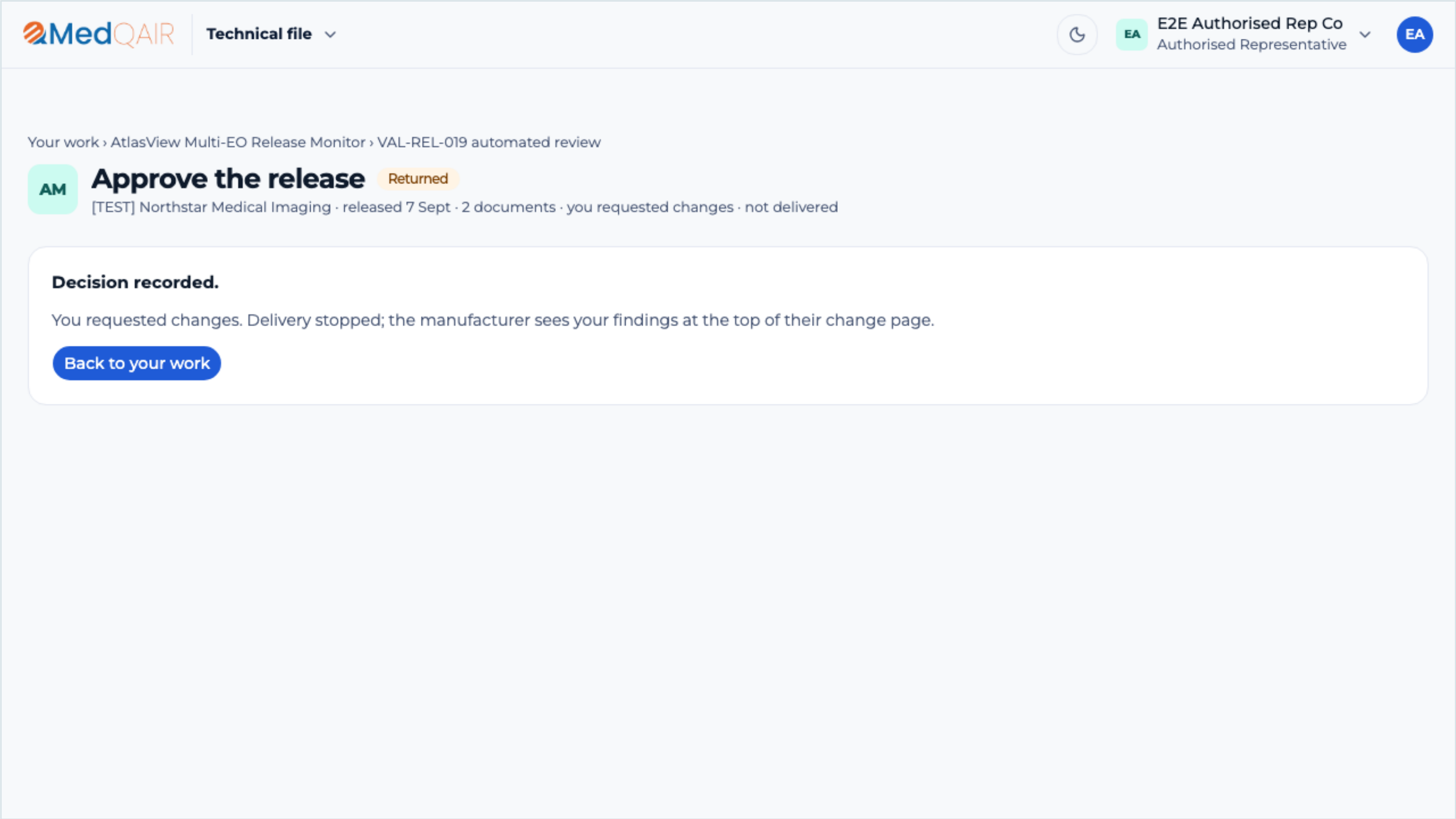
Request a correction

EXPECTED

Record a changes request with a reason against the frozen candidate.

OBSERVED / STEP PASSED

The approval-decision response is retained for later identity and audit checks.



And I request the anchored correction on the frozen release

Viewport extract: top 720 pixels of the original screenshot. The full original is embedded in the HTML companion.

Confirm the recorded decision

EXPECTED

The application must acknowledge the submitted decision.

OBSERVED / STEP PASSED

Decision recorded. is visible. Persisted decision attribution is checked again in step 36.

 **Technical file** 

  **E2E Authorised Rep Co**
Authorised Representative  

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

 **Approve the release** 

[TEST] Northstar Medical Imaging · released 7 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](#)

Then the anchored-feedback approval decision is durably recorded

Return to the manufacturer

EXPECTED

Continue in the original manufacturer's session.

OBSERVED / STEP PASSED

The acting session changes back to the manufacturer without reusing the reviewer's context.



Technical file 



TN

[TEST] Northstar Medical Im...
Manufacturer



EM

Home > AtlasView Multi-EO Release Monitor > Change 1

AM

Change 1

Waiting

Version VAL-REL-019 automated review follows VAL-REL-019 automated review released 7 Sept

 Documents 2 · 2 changed · frozen as released

 IFU & labelling

2 documents

multi-eo-product-label.pdf

New

 ...

eifu-multilingual.pdf

New

 ...

 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 · o...

Approvals, in order

1

E2E Authorised Rep Co

Approver · Asked now

Now



Delivery to 1 partner

Starts by itself on the last approval

When the Manufacturer resumes the anchored-feedback release

Reopen the stopped release

EXPECTED

Open the same tracked release after the changes request.

OBSERVED / STEP PASSED

The browser opens the retained release URL; the following step checks the feedback.







Home > Device > Change 1

DE

Change 1

Returned

Version VAL-REL-019 automated review returned 7 Sept by E2E Authorised Rep Co

Returned with findings; fix them in the next release

Start the next release

Withdraw release



Checking requested changes...



Documents

2 · 2 changed · frozen as released

Find



IFU & labelling

2 documents

multi-eo-product-label.pdf

New



...

eifu-multilingual.pdf

New



...



Registration

Checking...

Loading registration...

Open registration

Who receives it

Choose who

TH

[TEST] Harborline Importers

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

Approvals, in order

E2E Authorised Rep Co

Approver · Requested changes 7 Sept



Apply the anchored label correction in a later immutable release.

And I reopen the tracked release

Synthetic disposable-stack evidence | b275539ea53f | 7 September 2026

21

Read and answer the finding

EXPECTED

Find both threads, reply to the label finding and mark it addressed.

OBSERVED / STEP PASSED

The reply is stored and visible; the label thread is Addressed and the independent eIFU anchor remains visible.



Technical file

TN

[TEST] Northstar Medical Im...
Manufacturer

EM

Home > AtlasView Multi-EO Release Monitor > Change 1 > Feedback

AM

Feedback on Change 1

Returned

Open a finding at the spot it was raised and answer it there.

Back to the change

Findings, at the spot they were raised

multi-eo-product-label.pdf

eifu-multilingual.pdf

PDF review

Exact revision

Download

Page 1

E2E multilingual IFU - English / Nederlands

Per-document decisions

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

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

Export

Then the Manufacturer discovers and answers the anchored feedback

Start a correction successor

EXPECTED

Use the supported further-release path to correct the frozen attempt.

OBSERVED / STEP PASSED

A separate successor draft opens; the released attempt is not edited in place.



Technical file 



TN

[TEST] Northstar Medical Im...
Manufacturer

EM

Home › AtlasView Multi-EO Release Monitor › Change 2

AM

Change 2

Draft

follows VAL-REL-019 automated review released 7 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.
Documents

⚠

This market is outside your own country and needs a confirmed authorised representative — confirm it under Economic Operators.
Release authority & reviewers · recommended, does not hold release

✓

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

 Registration

Checking...

Loading registration...

Open registration

When I start the supported further-release remedy

Check the successor setup

EXPECTED

Keep the approver editable and reconcile saved audience counts.

OBSERVED / STEP PASSED

The UI counts match the saved selection and the approver remains editable. Counts alone do not prove recipient identities.

 **Technical file** 

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

Home > AtlasView Multi-EO Release Monitor > Change 2

AM

Change 2

Draft

follows VAL-REL-019 automated review released 7 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.**
Documents

 **This market is outside your own country and needs a confirmed authorised representative — confirm it under Economic Operators.**
Release authority & reviewers · recommended, does not hold release

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

 **Registration**

Incomplete

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

Answer remaining 37

Open registration

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

Synthetic disposable-stack evidence | b275539ea53f | 7 September 2026

24

Replace the affected revision

EXPECTED

Upload a corrected label while carrying the unaffected eIFU forward.

OBSERVED / STEP PASSED

Fresh release data identifies a new label revision and the unchanged eIFU revision.



Technical file 



TN

[TEST] Northstar Medical Im...
Manufacturer

EM

Home > AtlasView Multi-EO Release Monitor > Change 2

AM

Change 2

Draft

follows VAL-REL-019 automated review released 7 Sept

Discard draft

Release

 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 40045849



...

☐

eifu-multilingual.pdf



...

Showing 1 unchanged documents

Hide

Ready to release?

Ready



Every upload has a section.

Documents



This market is outside your own country and needs a confirmed authorised representative — confirm it under Economic Operators.

Release authority & reviewers · recommended, does not hold release



Waiting for one approval after release

E2E Authorised Rep Co · approval is required before delivery

 Registration

Incomplete

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

Answer remaining 37

Open registration

When I upload the corrected immutable successor revision

Synthetic disposable-stack evidence | b275539ea53f | 7 September 2026

25

Select the corrected delivery revision

EXPECTED

Explicitly select the corrected label for the importer.

OBSERVED / STEP PASSED

The current recipient picker saves the successor selection and fresh data confirms the corrected revision.



Technical file

TN

[TEST] Northstar Medical Im...
Manufacturer

EM

Home > AtlasView Multi-EO Release Monitor > Change 2

AM

Change 2

Draft

follows VAL-REL-019 automated review released 7 Sept

Discard draft

Release

Documents

2 · 1 changed

Find

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 40045849

1 unchanged documents

Show all

Ready to release?

Ready

✓

Every upload has a section.
Documents

⚠

This market is outside your own country and needs a confirmed authorised representative — confirm it under Economic Operators.
Release authority & reviewers · recommended, does not hold release

✓

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

Registration

Incomplete

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

Answer remaining 37

Open registration

And I keep the corrected revision in the configured delivery

Synthetic disposable-stack evidence | b275539ea53f | 7 September 2026

26

Release the successor once

EXPECTED

Submit the corrected candidate through one Release action.

OBSERVED / STEP PASSED

The successor is submitted once; its approval state is checked next.



Technical file 



TN

[TEST] Northstar Medical Im...
Manufacturer

EM

Home › AtlasView Multi-EO Release Monitor › Change 2

AM

Change 2

Draft

follows VAL-REL-019 automated review released 7 Sept

Discard draft

Releasing...

 Documents

2 · 1 changed

Find

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 40045849



...

1 unchanged documents

Show all

Ready to release?

Ready

✓

Every upload has a section.

Documents

⚠

This market is outside your own country and needs a confirmed authorised representative — confirm it under Economic Operators.

Release authority & reviewers · recommended, does not hold release

✓

Waiting for one approval after release

E2E Authorised Rep Co · approval is required before delivery

🌐 Registration

Incomplete

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

Answer remaining 37

Open registration

And I release this tracked candidate once

Synthetic disposable-stack evidence | b275539ea53f | 7 September 2026

27

Wait again for approval

EXPECTED

The correction must not bypass the blocking approval.

OBSERVED / STEP PASSED

The successor visibly waits for its blocking decision.



Technical file 



TN

[TEST] Northstar Medical Im...
Manufacturer

EM

Home › AtlasView Multi-EO Release Monitor › Change 2

AM

Change 2

Waiting

follows Change 2 released 7 Sept

 Documents

2 · 1 changed · frozen as released

Find

 IFU & labelling

1 document

multi-eo-product-label.pdf

Replaces previous

VAL-REL-019 corrected 40045849

 ...

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 · o...

Approvals, in order

1

E2E Authorised Rep Co

Approver · Asked now

Now



Delivery to 1 partner

Starts by itself on the last approval

Then delivery is visibly waiting for its blocking decision

Hand the correction to the reviewer

EXPECTED

Continue in the same representative's independent session.

OBSERVED / STEP PASSED

The retained reviewer identity is checked before the successor review.

 **Technical file** 

  **E2E Authorised Rep Co**
Authorised Representative  

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

 **Approve the release** 

[TEST] Northstar Medical Imaging · released 7 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](#)

When the authorised representative takes over the anchored-feedback review

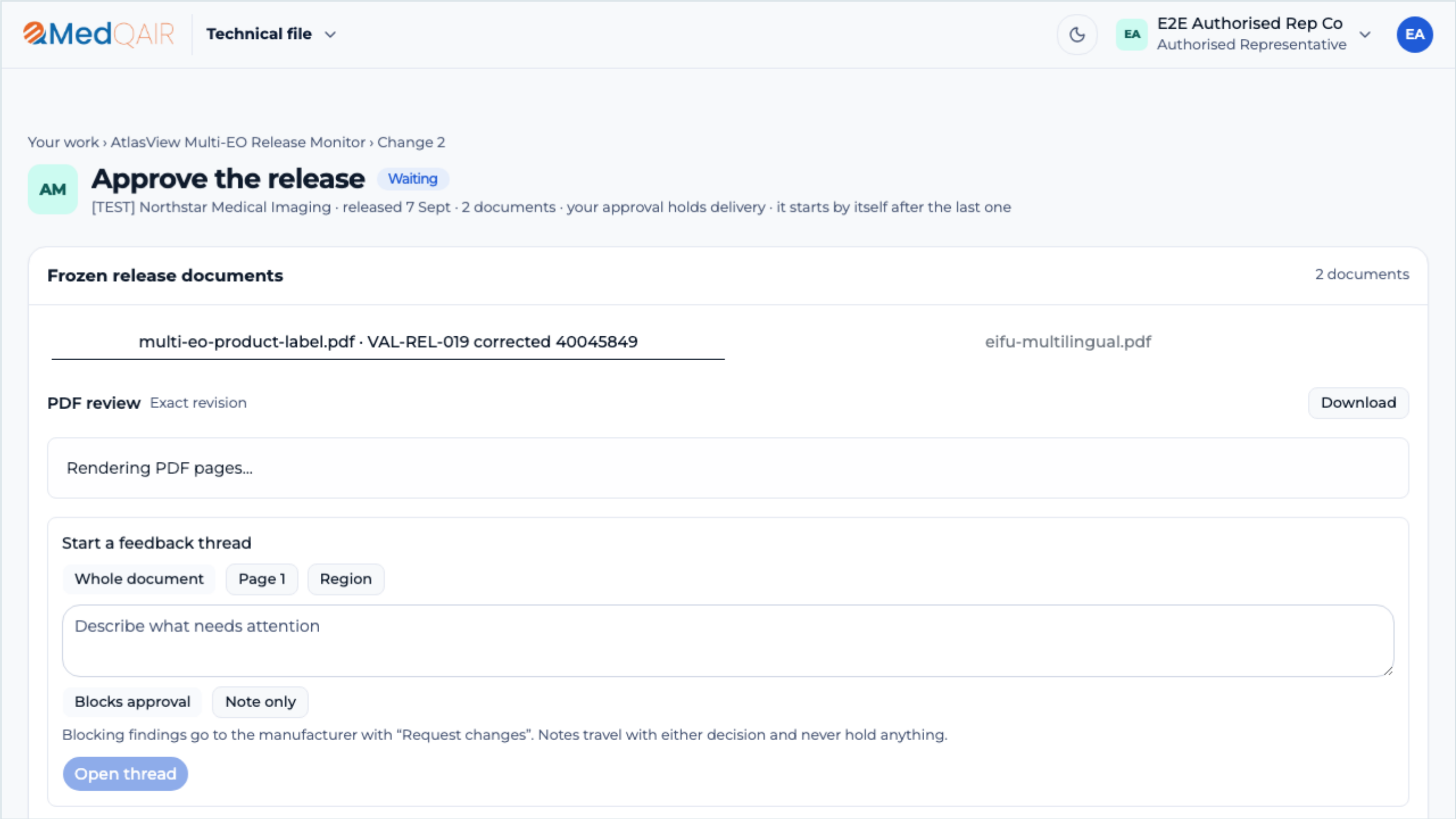
Open the successor approval

EXPECTED

Choose the exact successor from the work queue.

OBSERVED / STEP PASSED

The tracked successor's approval page and frozen documents are visible.



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

Viewport extract: top 720 pixels of the original screenshot. The full original is embedded in the HTML companion.

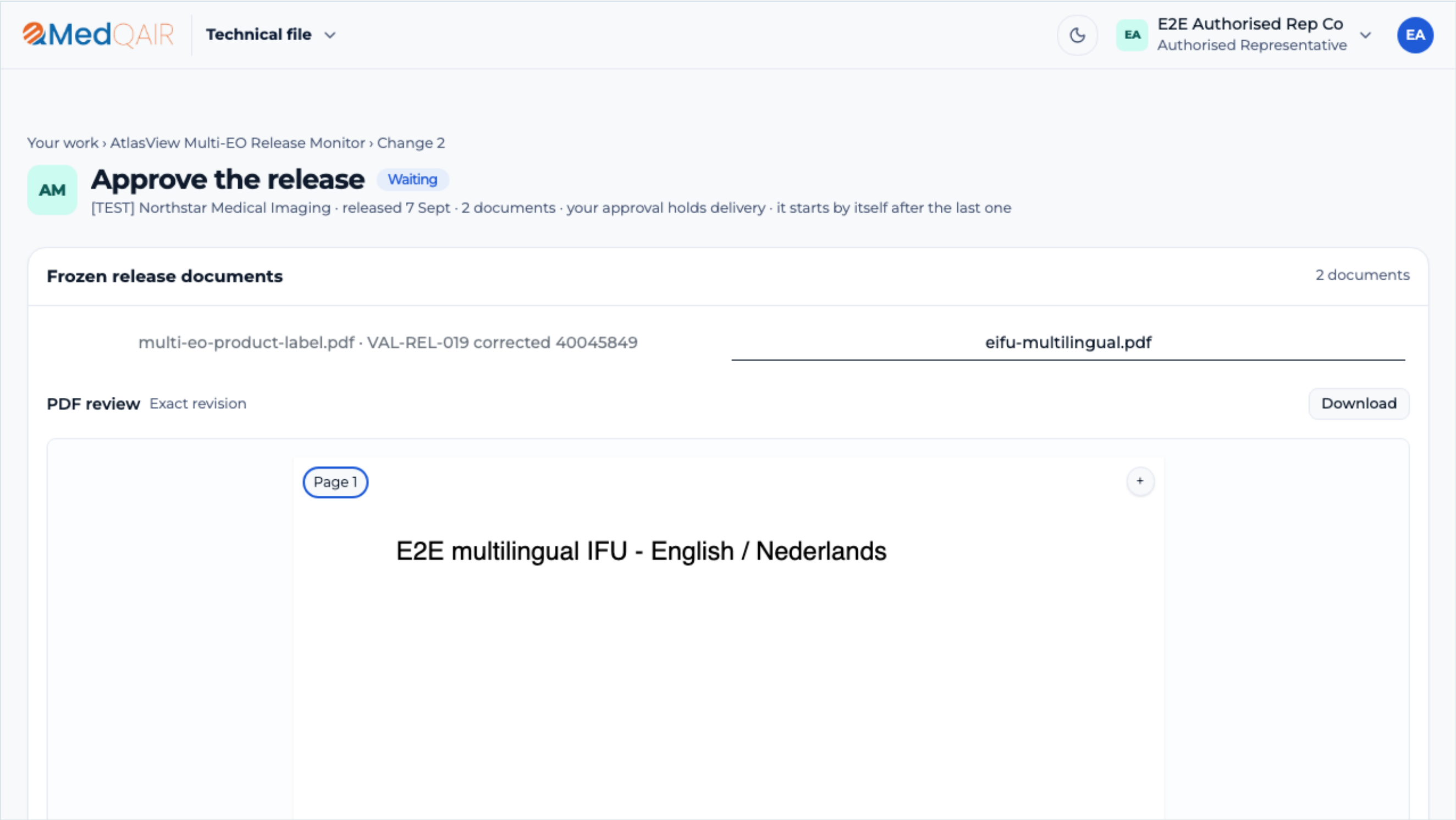
Review the carried finding

EXPECTED

Keep feedback lineage while preventing a stale anchor on the replacement PDF.

OBSERVED / STEP PASSED

The reply and origin survive. The old region anchor is absent on the replacement; the unchanged eIFU keeps its own anchor.



Then the reviewer sees the carried finding without a stale anchor

Viewport extract: top 720 pixels of the original screenshot. The full original is embedded in the HTML companion.

Resolve the corrected finding

EXPECTED

Resolve the carried label finding on the successor.

OBSERVED / STEP PASSED

The resolution request succeeds and the thread visibly reads Resolved.

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: 54823e4c-6a93-45a7-a15e-2a88d0e8dff3

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

When I resolve the carried anchored finding

Viewport extract: top 720 pixels of the original screenshot. The full original is embedded in the HTML companion.

Approve the correction

EXPECTED

Approve and record the successor's decision.

OBSERVED / STEP PASSED

The reviewer submits the approval through Record decision. This is a synthetic test decision.



Technical file



EA

E2E Authorised Rep Co

Authorised Representative

EA

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

Delivery starts by itself after the last approval.

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...

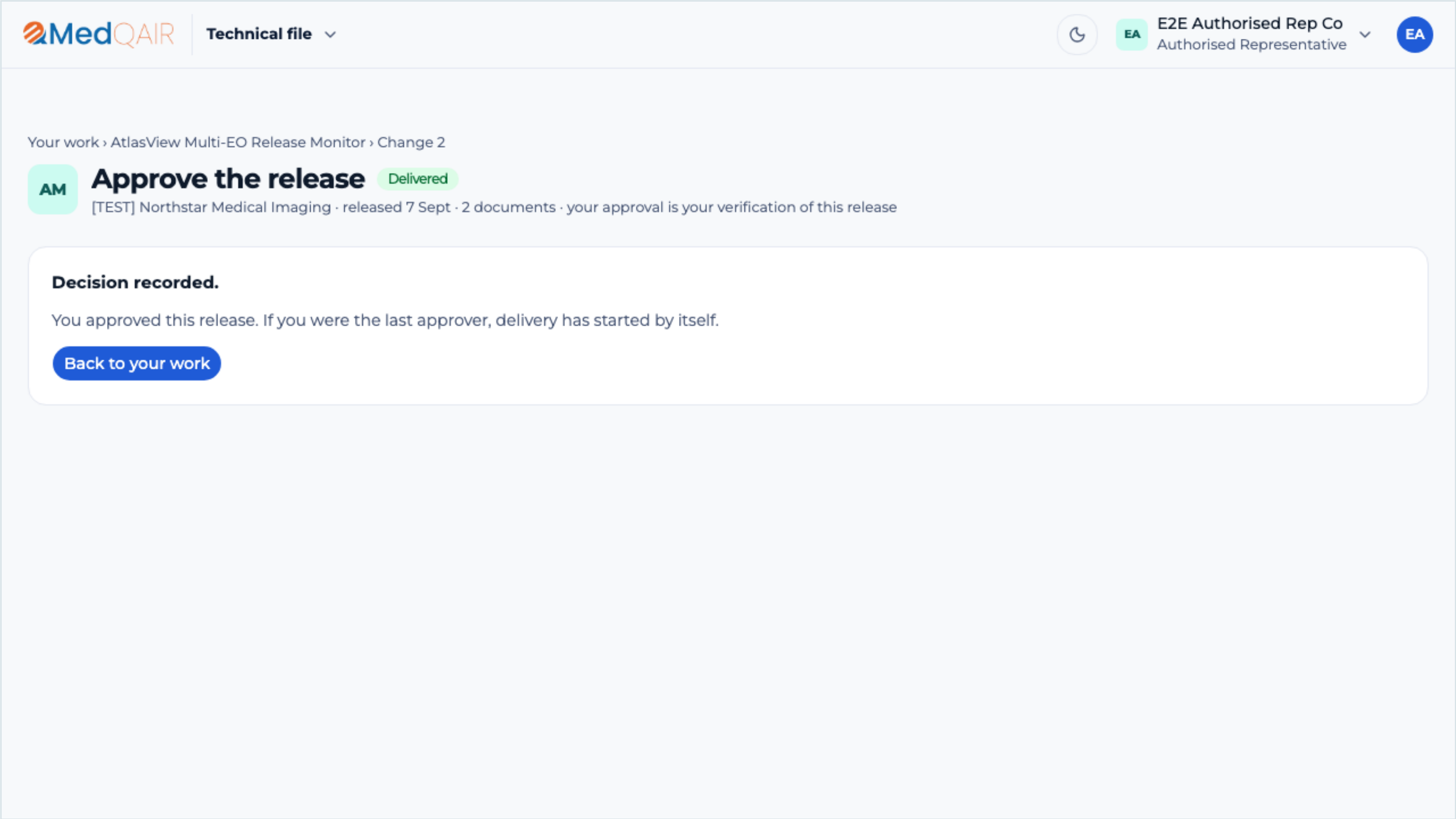
Confirm the approval was recorded

EXPECTED

Acknowledge the approved decision in the reviewer's view.

OBSERVED / STEP PASSED

Decision recorded. is visible; the exact persisted decision is checked in step 36.



Then the anchored-feedback approval decision is durably recorded

Return to delivery oversight

EXPECTED

Return to the manufacturer's existing session after approval.

OBSERVED / STEP PASSED

The manufacturer takes over without another Release action.

 **Technical file** 

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

Home › AtlasView Multi-EO Release Monitor › Change 2

AM

Change 2

Waiting

follows Change 2 released 7 Sept

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

 **IFU & labelling**

1 document

multi-eo-product-label.pdf

Replaces previous

1 unchanged documents

VAL-REL-019 corrected 40045849

 ...

Show all

 **Registration**

Incomplete

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Answer remaining 37

Open registration

Who receives it Choose who

 **[TEST] Harborline Importers**

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

Approvals, in order

1

E2E Authorised Rep Co

Approver · Asked now

Now



Delivery to 1 partner

Starts by itself on the last approval

When the Manufacturer resumes the anchored-feedback release

Synthetic disposable-stack evidence | b275539ea53f | 7 September 2026

35

Reopen the successor

EXPECTED

Open the exact successor to inspect its final state.

OBSERVED / STEP PASSED

The retained successor URL opens in ui-v2.





Home › AtlasView Multi-EO Release Monitor › Change 2

AM

Change 2

Delivered

follows Change 2 released 7 Sept

Documents

2 · 1 changed · frozen as released

Find

IFU & labelling

1 document

multi-eo-product-label.pdf

Replaces previous

VAL-REL-019 corrected 40045849

...

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 7 Sept

➤

Delivery

Delivered on 2026-09-07.

And I reopen the tracked release

Synthetic disposable-stack evidence | b275539ea53f | 7 September 2026

36

Observe automatic delivery

EXPECTED

The blocking approval must activate delivery without a second release action.

OBSERVED / STEP PASSED

The tracked successor is delivered after approval. The manufacturer has not pressed Release again.

MedQAIR

EM

Home > AtlasView Multi-EO Release Monitor > Change 2

AM

Change 2

Delivered

follows Change 2 released 7 Sept

Documents

2 · 1 changed · frozen as released

Find

IFU & labelling

1 document

multi-eo-product-label.pdf

Replaces previous

VAL-REL-019 corrected 40045849

...

1 unchanged documents

Show all

Registration

Incomplete

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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 7 Sept

Delivery

Delivered on 2026-09-07.

Then the tracked release is delivered without another Release action

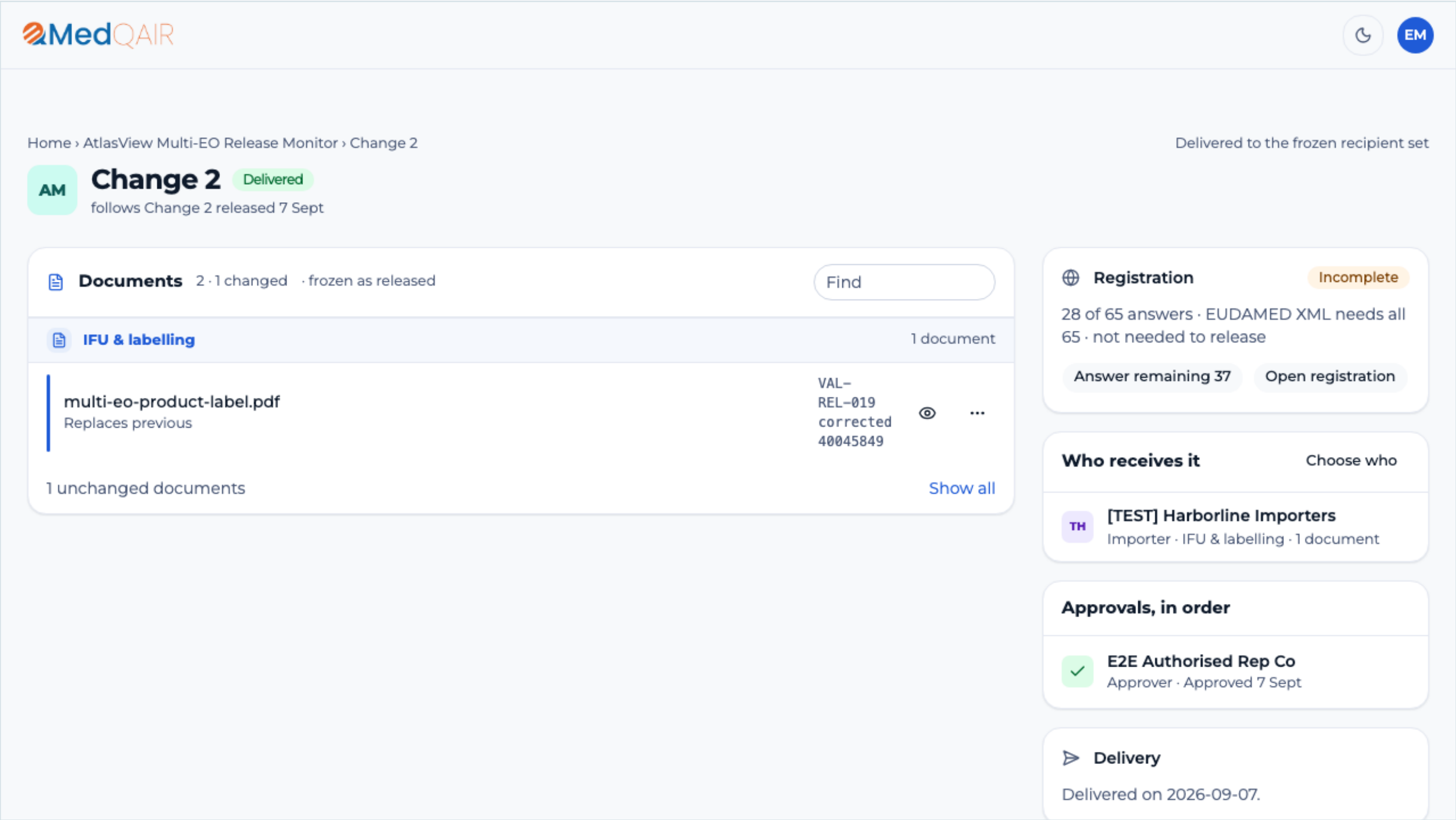
Reconstruct the retained history

EXPECTED

Fresh reads must preserve both attempts, decisions, actors, feedback lineage and final delivery.

OBSERVED / STEP PASSED

Persisted identity, audit, decision and feedback checks pass. The picture shows the final UI; the database facts come from assertions.



And fresh reads reconstruct the anchored-feedback release history

Switch to an unrelated company

EXPECTED

Use a separate company session for the isolation check.

OBSERVED / STEP PASSED

The acting session switches to the foreign manufacturer; the next steps test access refusal.



Technical file 



EF

E2E Foreign Manufacturer Co
Manufacturer

EF

Your work

E2E Foreign Manufacturer Co · Monday 7 September



0

drafts to finish



0

returned for changes



0

waiting on a partner



2

devices, 0 released

Needs you



Nothing needs you.

Devices · 2

All 2 



Name, UDI-DI or Basic UDI-DI

NU

Northgate Unrelated Ten...

Unreleased

FI

ForeignScope Imaging C...

Unreleased

When the unrelated Manufacturer takes over for the isolation check

Synthetic disposable-stack evidence | b275539ea53f | 7 September 2026

39

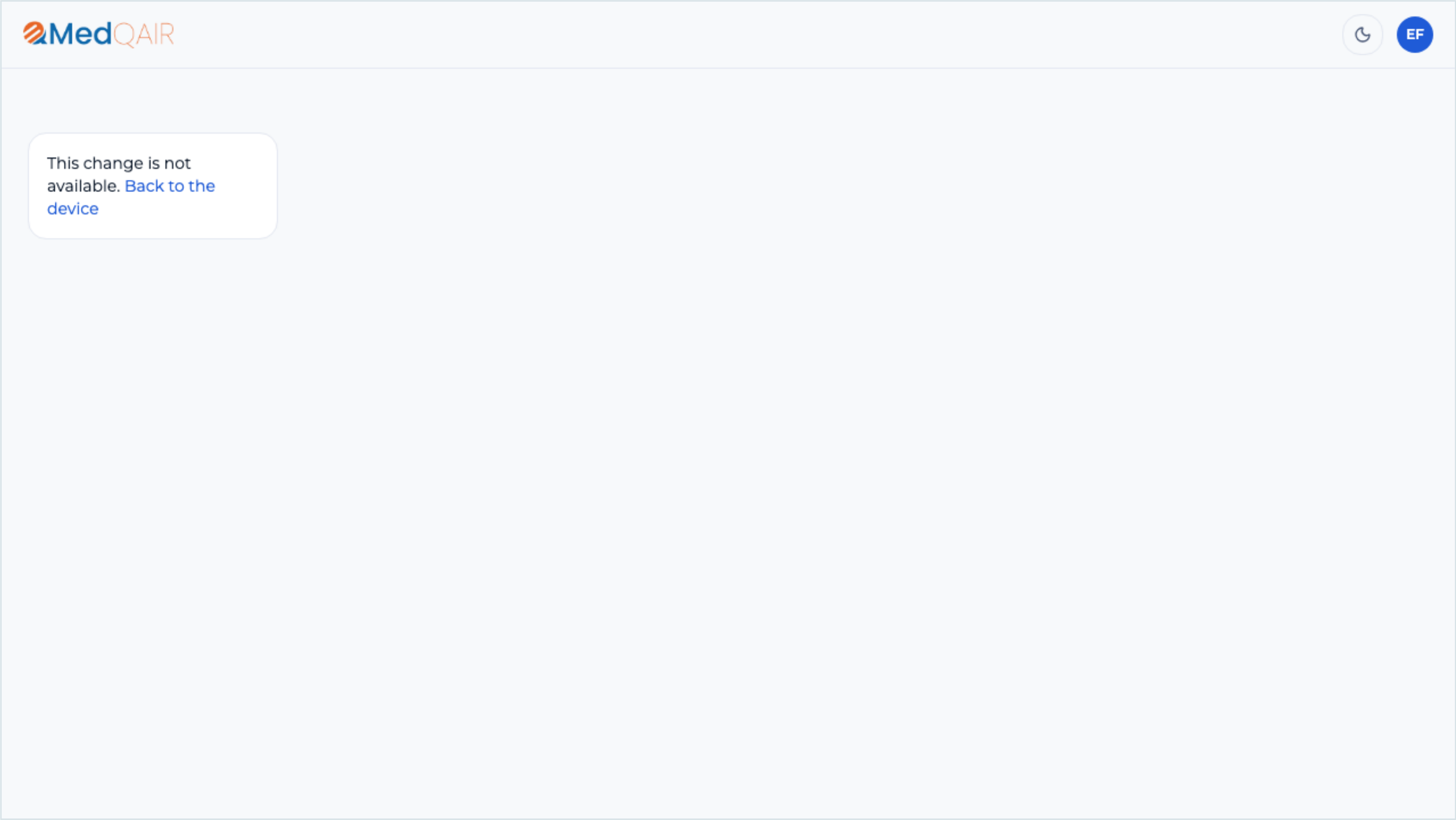
Attempt foreign reads and writes

EXPECTED

An unrelated company must not read or mutate this feedback.

OBSERVED / STEP PASSED

The scenario executes direct read and mutation refusal checks using the foreign session.

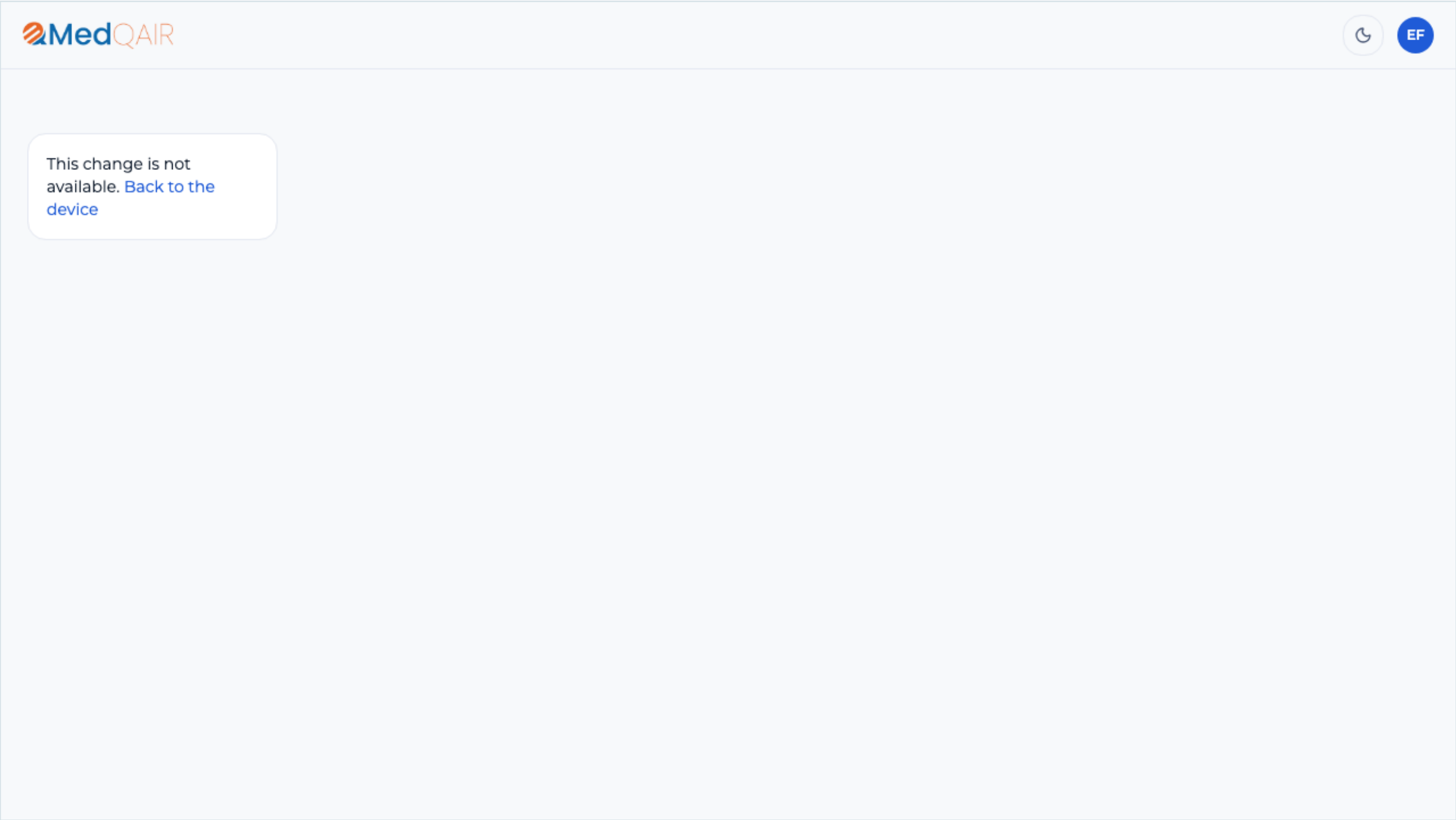


And I try to read and mutate the exact anchored feedback

Show the non-disclosing result

EXPECTED
The foreign UI must disclose no protected feedback and offer no lifecycle actions.

OBSERVED / STEP PASSED
The non-disclosing view and absence of lifecycle controls are asserted. This is the final negative-control step.



Then the foreign anchored-feedback view is non-disclosing and has no lifecycle actions

A passed story is one part of the evidence

Recorded machine result

The selected story passed all **39 steps**. The latest complete browser run at **ac5713498** recorded **70/71 normal tests passed (98.6%)**, 1 failed and 0 skipped. Its separate authentication lane passed **2/2**; combined, that is **72/73 (98.6%)**. The screenshots in this report come from the earlier focused run at **b275539ea5**; they are not relabelled as captures of ac5713498. The full-suite result and illustrated evidence therefore have distinct source identities.

Redesign coverage

The recorded screen-ledger baseline is **84 screens: 47 uncovered, 34 preview-only, 2 real-stack and 1 recorded**. A test can pass without proving an entire screen's acceptance criteria. This report does not promote a ledger row merely because a screenshot visits it.

Known limits

The nightly evidence receipt was not green at preparation time. No controlled User Requirement is yet recorded as fully validated. A complete requirement-level conclusion must come from the controlled validation-report reconciliation, not from this illustrated companion.

Revalidation

Reassess this evidence when the UI journey, approval semantics, permissions, schema, document revision behavior, deployment configuration or external interfaces change. This report identifies the exact tested source; it is not a claim about an unspecified later release.

One accessibility failure remains outside this passing story

Accessibility

A manufacturer releases with the keyboard: the existing Axe assertion reports serious text-contrast failures in the approval controls. Candidate text/monograms measured 3.52:1 and role controls 4.18:1 against the 4.5:1 requirement. The assertion remains enabled; the complete run is not qualifying.

Four earlier functional failures now pass

The fresh complete run passed frozen first-release withdrawal, starting a successor release, the unavailable add-device explanation, and the two-release correction-successor journey. The upload step was corrected to wait for transfer completion and the authoritative document row before editing or committing the release. These results supersede the four functional failures recorded at 92578a21e.

Approval-chain checks

The PRRC, authorised representative, importer and distributor obligations passed in this full run. These checks demonstrate their named assertions, not complete coverage of every screen or controlled requirement.

Separate capture and verification identities

Illustrations: **b275539ea53f70cb04466895853fe05c7fd62c86**, run **local-b275539ea5-20260907T172831Z**.

Latest complete suite: **ac571349833908a92626548a4ecc2e908e195763**, run **local-ac57134983-20260907T175944Z**. The remaining contrast issue requires a product fix and a new passing verification run.

Use this evidence in your own tool-validation record

1. Confirm your intended use

Record your organisation, MDIS environment and version, intended users, workflows and the records you rely on. Identify which parts of this demonstrated workflow apply to your use and which additional workflows need evidence.

2. Check configuration and differences

Compare your roles, approval policy, recipients, integrations and retention settings with the recorded test conditions. Record deviations and any additional checks on your configured environment. The supplier's synthetic test environment does not establish your local configuration.

3. Record your conclusion

Document acceptance criteria, applicable evidence, unresolved deviations, their impact and any required actions. Attach this report by its evidence-index hash. Keep the decision proportionate to the intended use and your quality-system process.

4. Review and approve

Client organisation: _____
Intended-use / validation record reference: _____
Environment and version: _____
Reviewer, decision and date: _____
Approval is deliberately left to the client's authorised reviewer.