

Product Label Approvals

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[Relates to version](#)

Tags: [10.4](#)

Product Label Approvals enable organisations to review and approve product labels before they are released for production use. Approvals cover both the layout of labels and the data that is displayed.

The approval process helps ensure that product labels are accurate, compliant with regulatory requirements, and reviewed by the appropriate personnel before use. Approvers can review label designs, reference materials, approval history, and supporting documentation before approving or rejecting a label.

As it is very common to have many product labels that reference a single label design version. The product label approval system allows you to batch together one or many of the product label versions associated with a given label design version within a single product label approval process, with shared reference documentation. This helps to streamline the approval process, whilst ensuring full compliance of each and every one of the product specific data being stored at product label level.

You can create a new approval to review one or more product labels using the **Label Approval Wizard**.

Four steps are required to get a product label version into production:

1. **Create the [label design](#).** Only production approved label designs can be assigned to a product to become that product's product label.
2. **Create the [product specific label version with product specific data](#).** When you create a new product label version, this will be in a draft state. To make this usable in production you can initiate the product label approval process which launches the **Label Approval Wizard** which guides you through the creation of an approval.
3. **Create a label approval.** When assigning a label design version and any associated product label versions to an approval these are immediately locked so what is being approved is controlled and cannot be changed. Product label versions move to a pending approval state.
4. **Execute the approval.** Once all the approval requirements have been accepted, the approval can be completed and all associated product label versions move to approved status and can be used in production.

This article covers **steps 3 and 4** only.

Prerequisites to creating a product label approval.

Before creating a label approval, ensure that:

- Product labels and label designs have been created.
- Any supporting documents needed for review are available.
- Approval requirements have been configured against the label design type.
- The appropriate approvers have been identified.

Product Label Approvals screen

Product label approvals can be managed from the **Product Label Approvals** screen.

Functions accessible from this page:

- **New Approval:** Launches the **Label Approval Wizard** which guides you through creating a product label approval.
- **Manage Approval:** Open the **Manage Approval Request** screen to approve/reject labels and monitor the status of

approval requests. Here you can send notifications to approvers and view a history of notifications.

- **Revision History:** View approval history which provides visibility into previous approval activity.
- **Abandon Approval:** When abandoning an approval, users can record a reason for the decision. This provides traceability and helps other users understand why the approval was discontinued.
- **Deleted Approvals:** View deleted approvals.

Create a Product Label Approval

A label design is of a specified type. The label type defines the approval requirements, including who needs to approve what.

The **Label Approval Wizard** introduces a guided workflow for creating and managing product label approvals.

The wizard supports two activities: creating a new label approval or amending an existing draft label approval.

Users are taken through a structured six-step process that ensures all required information is collected in the correct order.

It also enables a single approval to include multiple product label versions for a designated label design version.

When creating an approval:

1. Enter a change reference and select a label design and version.
2. Select the product label versions to include in the approval (note these must all be of the specified label design version).
3. Add label verification images.
4. Add any required supporting documentation.
5. Review and confirm the approval.
6. Send notifications to approvers.

Label Approval Wizard - Create a Product Label Approval

The **Label Approval Wizard** is designed to support the creation of a new product label approval, adding product label versions to an existing draft approval, and enabling a single approval to include multiple product label versions.

To create a new product label approval, launch the **Label Approval Wizard** from the **Product Label Approvals**, **Label Design**, or **Product Label Management** screens.

Draft Product Label Approval

Change Reference

Label Approval Wizard

Draft

1. Change Reference

2. Select Product Labels

3. Label Verification Images

4. Supporting Documents

Confirm

5. Review & Confirm

Notify

6. Send Notifications

Approval Content Summary

Product label versions linked to this label design version

Assigned to this approval

Missing label verification image

Change Reference

Link this approval to a change control record, then select the label design and version

Change Reference

e.g. CR-2026-0041

Label Design

Label Design Version

The change reference links the approval to a change control record.

- 1. Change Reference*:** Provide a change reference. Product label approvals can be linked to a QMS authorisation or they can be created independently of a QMS authorisation. Note that it might be common to have more than one product label approval linked to a single QMS authorisation. This is OK as the system will automatically generate a unique ID for each label approval so you can have multiple approvals linked to the same change reference.
- 2. Label Design*:** Select a label design.
- 3. Label Design Version*:** Select a label design version (note that only production approved versions are available to be selected).

Select Product Label Versions

Label Approval Wizard (Change Reference / Approval ID: SA1407-1/346, Label Design: Dental box label (v. 1))

Draft

1. Change Reference

2. Select Product Labels

3. Label Verification Images

4. Supporting Documents

Confirm

5. Review & Confirm

Notify

6. Send Notifications

Approval Content Summary

1 Product label versions linked to this label design version

1 Assigned to this approval

0 Missing label verification image

Select Product Labels

Select draft product label versions to include in this approval.

Product Type

Product

Product Label Version

Unassign

	Product	Product Label Version	Last Modified	Assigned
☒	box of 10 dental implants	1	14/07/2026 14:15:07	Yes
☐	Dental Implant	1	14/07/2026 16:17:49	No

Page Size

20

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Next: Label Verification Images

Product label versions can be added to an approval during creation. The list is automatically filtered so that only product

label versions belonging to the selected **Label Design Version** are displayed. When a product label version is added to an approval, its approval status changes to Pending approval.



Note

The label design version must have been assigned to the product in the **Product Label** screen for it to appear in the **Select Product Labels** screen.

Approval Content Summary

The wizard contains an **Approval Content Summary** section that provides a summary of the approval highlighted in grey, blue and yellow. This gives you a view of where you are and helps identify where there might be a gap.

- **Product label versions linked to this label design version** : Tells you how many product label versions you have for the label design version.
- **Assigned to this approval**: Tells you how many are assigned to this approval. For example, you have 1000 in the system (bullet point above) and I'm approving 900 of them (this bullet point), you can investigate what's happened to the other 100 if required.
- **Missing label verification image**: Highlights if a verification image is missing because every product label version must have one to be included in the final approval.

Label Verification Images

Label Approval Wizard (Change Reference / Approval ID: SA1407-1/346, Label Design: Dental box label (v. 1))

Draft

1. Change Reference

2. Select Product Labels

3. Label Verification Images

4. Supporting Documents

Confirm

5. Review & Confirm

Notify

6. Send Notifications

Approval Content Summary

1 Product label versions linked to this label design version

1 Assigned to this approval

0 Missing label verification image

Label Verification Images

Build generate for multiple label versions using one set of values

What is a label verification image?

A visual standard for operators to compare against what they're about to print. Not physically printed - stored against the label version

What does this screen do?

Generates label verification images for all product label versions that are missing one.

Show Missing Label Verification Images Only

All

Refresh

View

Generate

☒	Product	Product Label Version	Last Modified	Reference Image
☒	box of 10 dental implants	1	14/07/2026 14:11:07	Present

< > >>

Page 1 of 1

20 items per page

1 - 1 of 1 items

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Next: Supporting Documents

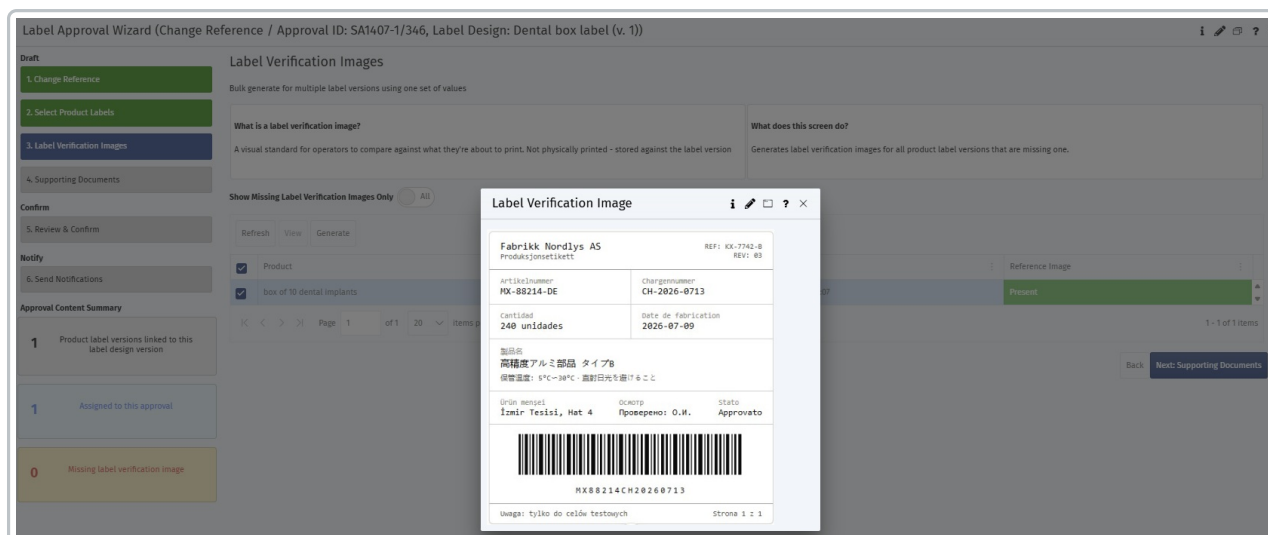
Label verification images are used during manufacturing execution to verify label accuracy. Operators can compare either the label image before printing or the physical label after printing against the approved verification image to confirm that it meets requirements. Verification images are approved as part of the label approval process.

Providing operators with the ability to compare the print image with the approved verification image before a print job is sent to the printer helps prevent invalid labels from being produced. Identifying issues before printing reduces reconciliation effort, minimises waste, and lowers the risk of regulatory compliance issues.

The **Label Verification Images** page is used to create visual representations of the selected production-approved label versions that can be reviewed during the approval process. This tool allows you to multi-select product label versions and create the corresponding verification images for each with a single transaction.

By default, the grid shows only product label versions that do not yet have a label verification image. You can generate images for one or multiple selected rows. After images are generated, they become associated with the relevant product label versions.

Supporting Documents



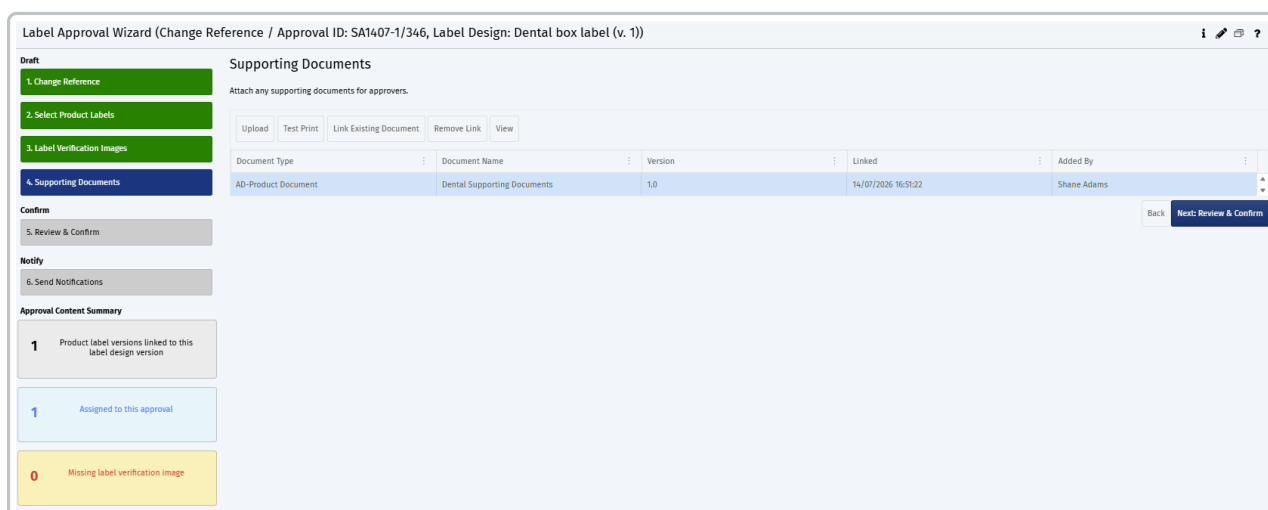
The **Supporting Document** pop-up lets you add documents that support the approval process, such as specifications, example test print images, change control forms and related product documentation. Note that only documents of a controlled type are able to be assigned to approvals to ensure no uncontrolled changes.

Functions available include:

1. Uploading new documents.
2. Linking existing product documents.
3. Running test prints against the labels included in the approval.

The test print functionality is restricted to product label versions that are part of the current approval. Product labels outside the approval cannot be selected.

1. Supporting Documents



Confirm the Product Label Approval

Review & Confirm

Label Approval Wizard (Change Reference / Approval ID: SA1407-1/346, Label Design: Dental box label (v. 1))

Draft

1. Change Reference

2. Select Product Labels

3. Label Verification Images

4. Supporting Documents

Confirm

5. Review & Confirm

Notify

6. Send Notifications

Approval Content Summary

1 Product label versions linked to this label design version

1 Assigned to this approval

0 Missing label verification image

Review & Confirm

Review the approval summary before submitting.

Change Reference: SA1407-1
Product Label Versions: 1
Approval ID: 346

Label Design: Dental box label (v. 1)
Supporting Documents: 1
Approval Status: Draft

⚠ Once confirmed, 1 product label versions will move to Pending approval and cannot be edited until resolved.

Back Confirm & submit approval

The **Review & Confirm** step provides a summary of the approval before it is completed. This includes:

- The approval eader ID.
- The number of associated product label versions. Note that the user can also view the number of available product label versions that use the specified label design version as a check to ensure that none have been inadvertently left out.
- Number of supporting documents linked to the approval.

You can review the information and confirm the approval configuration.

After confirmation:

- The approval is updated to Pending status.
- No further changes to the approval can take place.

Notify Approvers

Send Notifications

Label Approval Wizard (Change Reference / Approval ID: SA1407-1/346, Label Design: Dental box label (v. 1))

Draft

1. Change Reference

2. Select Product Labels

3. Label Verification Images

4. Supporting Documents

Confirm

5. Review & Confirm

Notify

6. Send Notifications

Approval Content Summary

1 Product label versions linked to this label design version

1 Assigned to this approval

0 Missing label verification image

Send Notifications

Select who should be notified when this approval is submitted

Notify Approvers

Name	
Third DS Requirement	
First Requirement	
Fourth Requirement	
Second Requirement	

Select Users

Full Name: shane Search

Additional notes for the approval notification

Email Content

Send notification

☒	Name
☒	Shane Adams (shane.adams@mestec.net)

The **Select Users** screen lets you send email notifications to approvers for each of the approval requirements informing them of the product labels they need to approve. Users must have the required permissions as defined in the label type to approve the label.

The **label type approval requirement** is configured with the permission required for approving product labels of a specific type.

Manage Approval Request

An approver can access their outstanding approvals in one of the following ways:

- Click the link in the email received and use the **Change Reference** and ID to find the approval.
- Navigate to the **Product Label Approvals** page, toggle on **My Approvals** and apply filters as required, and click **Refresh** to view just your approvals. Select the approval and click **Manage Approval**.

Manage Approval Request

Approval Summary

View Label Design

View Product Label

Images & Docs

Change Reference: SA1407-1

Product Label Versions: 1

Approval ID: 346

Label Design: Dental box label (v. 1)

Supporting Documents: 1

Approval Status: Pending Approval

0

4

0

Approved

Pending

Rejected

Approval Requirements

Respond

Response History

Notify Approvers

Notification History

Requirement	Permission Required	Status	Notification Status	Responded By	Evidence Documents	No. of Revision	Comments
First Requirement	Approve Product Label From Pending	Pending	Last Sent 14 JUL 2026		No	4	
Third DS Requirement	Approve Product Label From Pending	Pending	Last Sent 14 JUL 2026		No	4	
Fourth Requirement	Approve Product Label From Pending	Pending	Not sent		No	4	
Second Requirement	Approve Product Label From Pending	Pending	Not sent		No	4	

Abandon Approval

Final Sign-Off

Cancel

The **Approval Summary** displays information related to the approval and green, amber and red tiles showing approved, pending and rejected signatures. You can also access relevant screens:

- **View Label Design:** Navigates to the Label Design screen
- **View Product Label:** Navigates to the Product Label screen.
- **Images & Docs:** View images and documentation relevant to the approval.

The **Approval Requirements** section allows an approver to select a requirement and respond with an approval or rejection of the approval.

Manage Approval Request

Approval Summary

View Label Design

View Product Label

Images & Docs

Change Reference: SA1407-1

Product Label Versions: 1

Approval ID: 346

Label Design: Dental box label (v. 1)

Supporting Documents: 1

Approval Status: Pending Approval

0

4

0

Approved

Pending

Rejected

Approval Requirements

Respond

Response History

Notify Approvers

Notification History

Requirement	Permission Required	Status	Notification Status	Responded By	Evidence Documents	No. of Revision	Comments
First Requirement	Approve Product Label From Pending	Pending	Last Sent 14 JUL 2026		No	4	
Third DS Requirement	Approve Product Label From Pending	Pending	Last Sent 14 JUL 2026		No	4	
Fourth Requirement	Approve Product Label From Pending	Pending	Not sent		No	4	
Second Requirement	Approve Product Label From Pending	Pending	Not sent		No	4	

Abandon Approval

Final Sign-Off

Cancel

Review Label Data Approval Request

Approval ID: 346, Change Reference: SA1407-1, Requirement: Second Requirement

Approval Decision

Approve

Comments

Evidence Documents

Link Existing Document

Upload

Test Print

Document Name	Version	Linked	Uploaded
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Close

Sign And Save

To provide evidence for an approval / rejection, an approver can link an existing document or upload a new document. They

can also print a test label.

Once all approvers have accepted the required approval steps, the label approval can be completed and the status of all associated product label versions is automatically updated from **Pending Approval** to **Approved**.

If an approval requirement is not met, an approver can reject the request. In this case, the approval must be abandoned, and all associated product label versions are returned to **Draft** status so that the approval process can be restarted. Any approval decisions and audit history recorded during the process are retained and are not lost.
