Managing applications with multiple devices

Overview

Medical devices can be added to an application through the use of multiple device upload templates. A maximum of 3,000 devices is possible per bulk upload. It is recommend you use the bulk upload template if your application includes 5 or more devices.

There are two templates that are available:

- Medical Device Template: for devices pertaining to MDR, UKCA parts 2 and 3 services.
- In Vitro Device Template: for devices pertaining to IVDR, IVDD and UKCA Parts 4 services.

Step 1 → Downloading a template

You are able to download the templates in two places:

- The Select Services section of their application, once you have selected a relevant service .
- The Add Devices section when you select ADD MULTIPLE MEDICAL DEVICES or ADD MULTIPLE IN VITRO DEVICES.

Downloading a template from the Select Services section

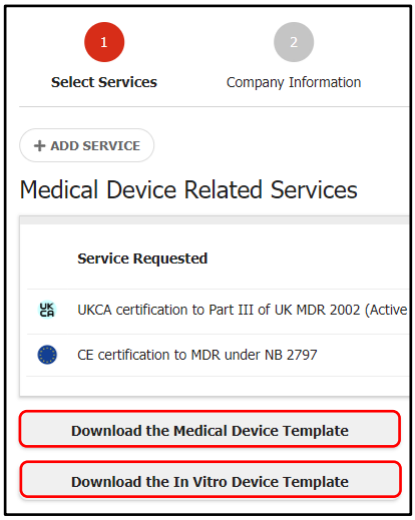
Navigate to Select Services section of the application.

If you have selected medical device related services: click Download the Medical Device Template.

If you have selected In Vitro device related services: click Download the Medical Device Template.

The template document is downloaded, ready to edit.

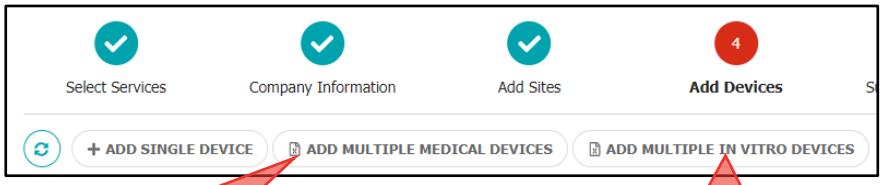
Note: These options will only display if your selected services include medical devices or In Vitro devices.

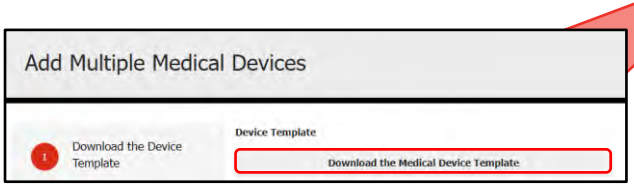


Downloading a template from the Add Devices section

Navigate to Add Devices section of the application.

Click ADD MULTIPLE MEDICAL DEVICES or ADD MULTIPLE IN VITRO DEVICES.





The Add Multiple Medical Devices page displays.

Click Download the Medical Device Template.

The template document is downloaded, ready to edit.

The Add Multiple In Vitro Devices page displays.

Click Download the In Vitro Device Template.

The template document is downloaded, ready to edit.

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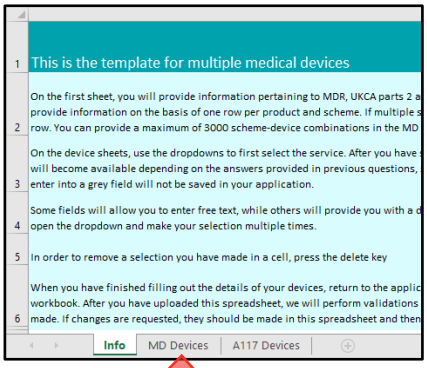
Step 2 → Populating the multiple device upload template

Note: this quick card will reference the populating of the Medical Device template but the process is exactly the same for the In Vitro device template

Open the multiple device upload template in Microsoft Excel or compatible spreadsheet software.

The template is broken down into three worksheets:

- Info: this tab has guidance text for the client to assist their successful population of the template.
- MD Devices: for providing details of devices related to MDR, UKCA parts II and III services.
- A117 Devices: for providing details of devices related to Article 117.



Click the MD Devices tab.

Populate the details of the devices from Row 6 onwards of the worksheet.

Enter the following details:

Column A: select the type of medical device from a drop-down list of the following options:

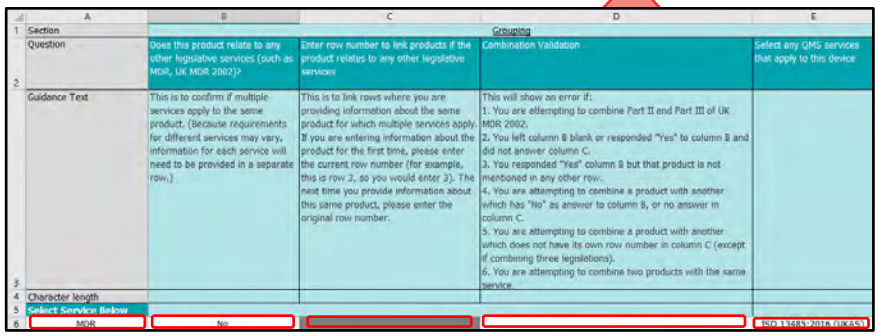
- MDR
- Part II of UK MDR 2002
- Part III of UK MDR 2002

Column B: Select either Yes or No from the drop-down list to confirm if more than one service is related to the device.

Column C: Enter a row number to link the device to rows where you are providing information about the same product for which multiple services apply.

Column D: This displays either OK or ERROR.

This feedback displays to indicate to you if your previous selections in columns B and C are valid choices.



Each column recorded in the spreadsheet represents information that would be captured about a device within the portal if it was entered directly. Row 2 for each column displays the question and Row 3 provides guidance on what the information should be.

The remaining columns on the row are populated with the following details.

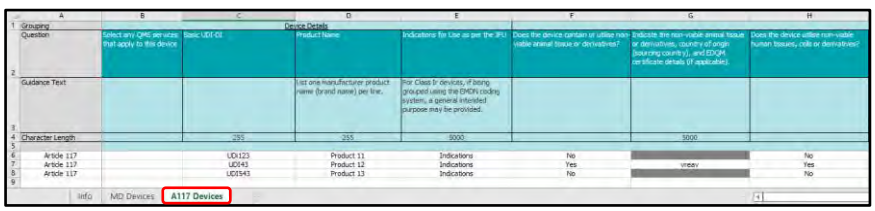
- Columns H-M: Device details
- Columns N-R: Classification
- Columns S-AB: Special materials
- Columns AC-AG: Novelty /Material Base / Technology
- Columns AH-AL: Sterilisation
- Columns AM-AT: Device Attributes
- Columns AU-AV: Technical Documentation

Once all the details for that row have been populated. The process can be repeated on a new row for each device.

Note: if you enter data that is incorrect or too many characters for that field you will receive an error message in excel to correct it.

Click the A117 Devices tab.

Enter the details for any A117 devices from row 6 onwards.



It is recommended once you have recorded all device details, to save the template with a unique name (such as your company name, version number and date of creation).

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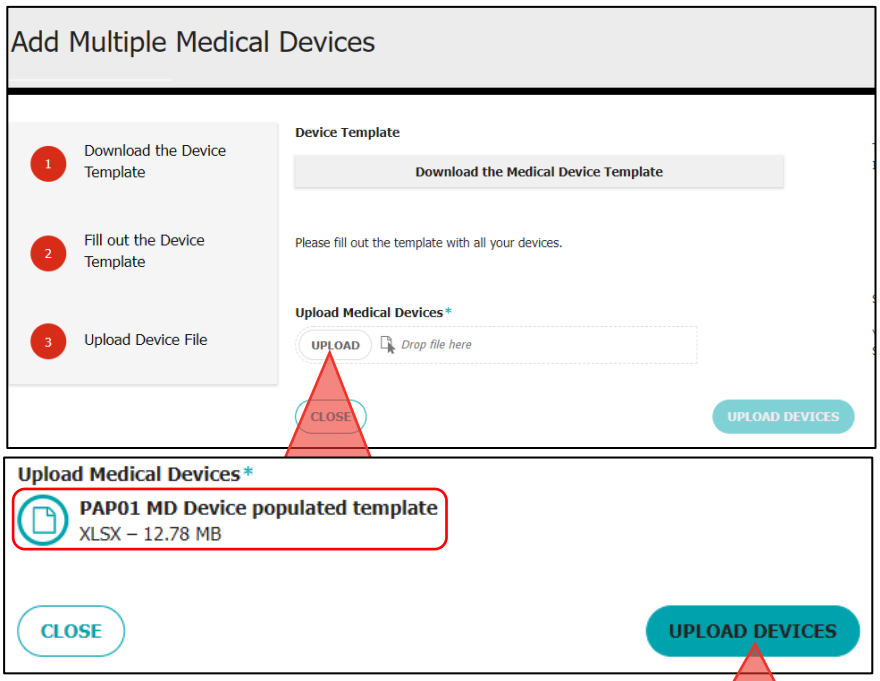
Step 3 → Uploading the bulk upload template

Once a template has been populated it can be uploaded directly to the digital pre-application portal.

Enter the following details from the Add Multiple Medical Devices page or the Add Multiple In Vitro Devices page.

Upload Medical Devices: click UPLOAD and select the populated template.

Note: the spreadsheet software, version or operating system that you use has no effect on the compatibility of the template.



When the template has finished uploading, the file type and size displays.

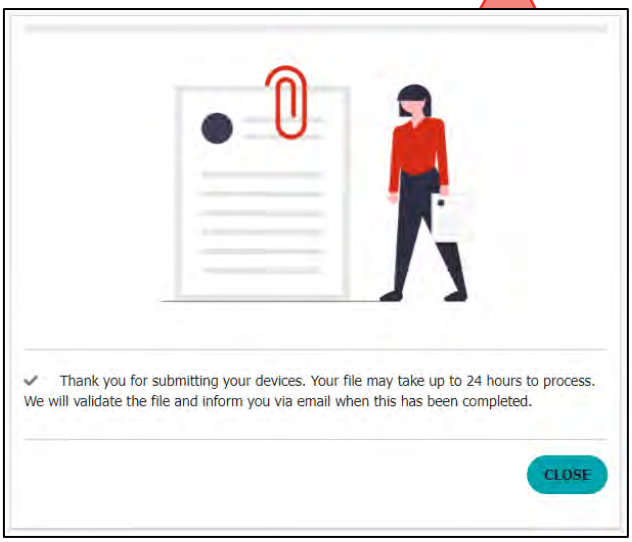
Click UPLOAD DEVICES.

If the uploaded template contains one or more devices that are linked to services not already registered on the application.

An error message will appear, and the process must be repeated with the error resolved by either adding the service to the application or removing the reference to the service in the multiple device upload template.

If there is not an error, a confirmation message displays.

Click CLOSE.



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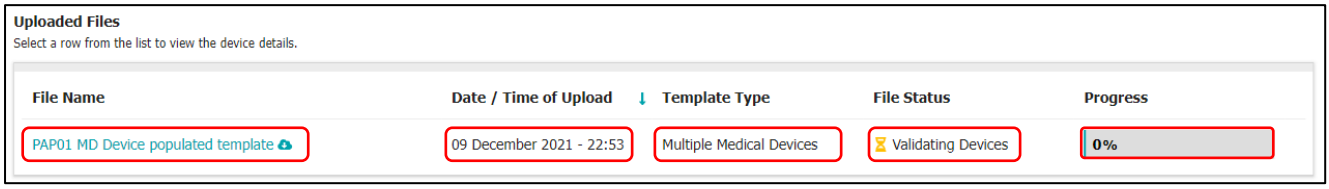
Tracking validation progress of uploaded devices

When the client closes the confirmation message of the upload, they are returned to the Add Devices section of the application where a new section displays on the page: Uploaded Files. Once an upload has been successful the template will be validated by the portal.

The maximum processing time for this validation is 24 hours, however it is likely to be less than this, the range of time depends on how many devices have been included in the template (up to 3,000 devices in one upload) and how many other clients are uploading multiple device upload templates at the same time.



File Name: the file name of the uploaded template. Click the file name to download a copy of the original upload.

Date / Time of Upload: displays the exact date and time that the template was successfully uploaded.

Template Type: This column displays the type of template, which can be either Multiple In Vitro Devices or Multiple Medical Devices.

File Status: This displays the current status of the file which can be Validating Devices, Completed with Errors and/or Advisories or Completed with No Errors and/or Advisors.

Progress: The progress bar displays a percentage of the devices in the template that have been processed so far.

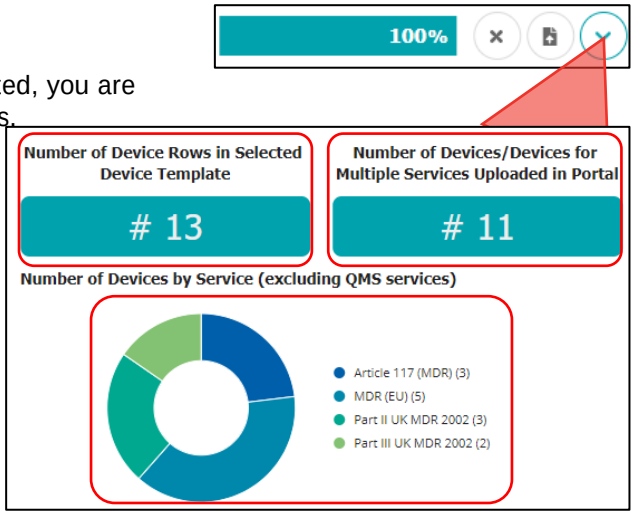
The progress bar updates every 50 devices that have been processed. For example, if you have uploaded 200 devices in the template it will potentially display as 0%, 25%, 50%, 75% or 100%.

Click the Refresh icon to check the progress of the template process without reloading the platform.

Note: while a template is being processed, no further templates can be uploaded or individual devices can be added.

When the template is successfully validated, the list of devices included in the template display in the device list. This is a good opportunity to inspect the devices details and ensure that they have been imported correctly.

Viewing validation statistics



When the multiple device upload template has been validated, you are able to view statistics of the uploaded and validated devices.

Click the Chevron symbol next to the uploaded file.

Number of Device Rows in Selected Device Template: displays the number of devices rows that were originally entered in the template.

Number of Devices/Devices for Multiple Services Uploaded in Portal: displays the number of devices that were uploaded for one or more services.

Number of Devices by Service (excluding QMS services): a chart displays the proportion of devices that were uploaded for each service.

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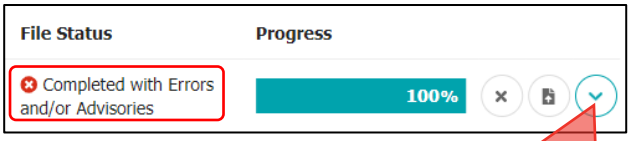
Dealing with errors and advisories

If any errors or advisories notes were generated from the validation, click the Chevron symbol to view them.



Search: enter the name of products to filter the errors and advisories to matching products.

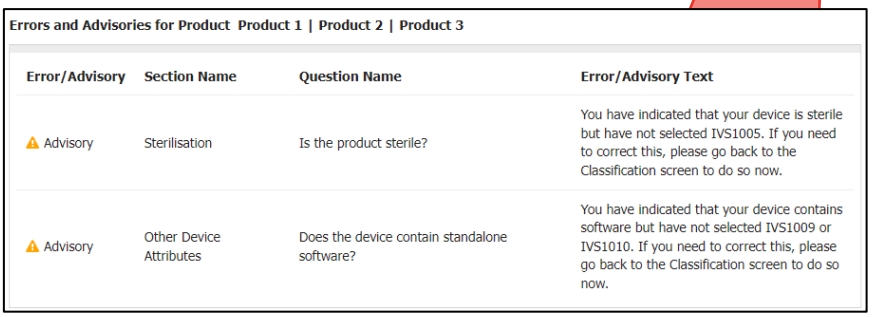
Product Name: name of the product that have any errors or advisories.

Services: service(s) that are linked to the product.

Advisory Count: the number of advisory notes recorded for the device.

Error Count: the number of error notes recorded for the device.

Click the Chevron icon next to any line to view the Advisory and/or error notes in more detail.



Error/Advisor: Displays either Advisor or Error.

Section Name: the section of the application that the advisory or error note relates to.

Question Name: displays the question that the error or advisory note relates to.

Error/Advisory Text: Displays what the nature of the error is or why an advisory or error note was generated.

Deleting a multiple device upload template

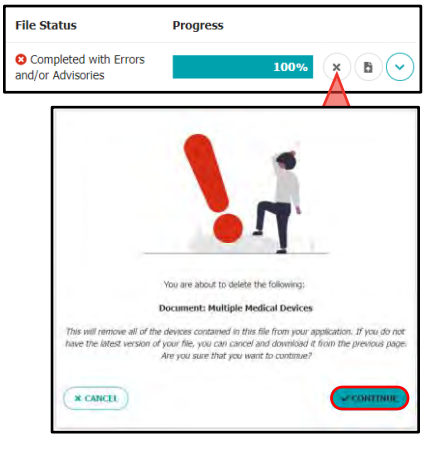
If there are mistakes in the uploaded template, you can remove it along with any successfully created devices.

Click Delete Document.

A confirmation screen displays to either confirm or cancel or the deletion of the document.

Click CONTINUE.

The uploaded template is removed and all associated devices.



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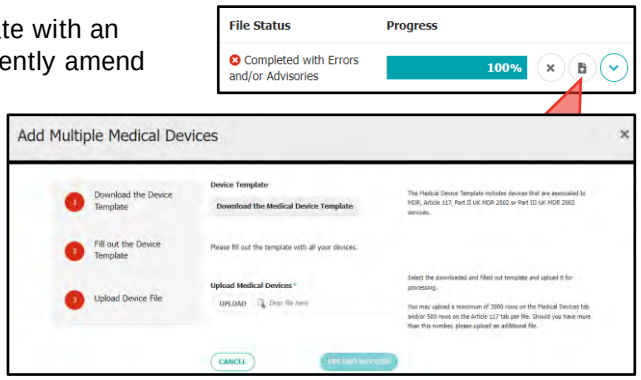
Replacing a multiple device upload template



You can replace the original multiple device upload template with an amended template in one step. This allows you to conveniently amend the template for any encountered errors or advisories.

Click Replace Devices.

The Add Multiple Medical Devices or Add Multiple In Vitro Devices page displays.

Repeat Steps 2-3 of the process.

The newly uploaded template replaces the original template.

Note: when a template is replaced, previous versions of the template are kept on the platform for auditing purposes.