Medicines & Healthcare products Regulatory Agency

MHRA Designated Standards Prioritisation

Introduction

The Medical Devices Regulations 2002 (MDR 2002) has designated certain standards as technical specifications for medical devices and in vitro diagnostic (IVD) devices. The Medicines and Healthcare products Regulatory Agency (MHRA) is working to deliver a future regulatory framework for medical devices that prioritises patient and public safety, gives patients access to the medical devices they need, and ensures the UK remains an attractive market for medical technology innovators. The MHRA is seeking your valuable input through this survey on the prioritisation for designation of device standards that support compliance with the MDR 2002.

This survey will inform which standards the MHRA should prioritise for designation and covers:

- the standards designated that your organisation relies on
- the standards not designated that your organisation relies on and would most like to see designated

Please note, this survey is open until **11:59pm on Tuesday 30 September 2025**.

Information for respondents

This survey is designed so you can skip questions and/or opt to answer only certain sections. You do not need to complete your response in one sitting. To resume the survey, click the same link and you will be able to come back to it at another time to finish it off.

Once you have completed the survey, please submit your response by **11:59pm on Tuesday 30 September 2025**.

Please note, this survey has been designed to show or hide certain sections and/or questions depending on your answers to previous questions.

This survey is focused on use of standards for devices being placed on the **Great Britian (GB) market**.

For any questions relating to this survey, please email info@mhra.gov.uk with “Designated Standards Survey” in the subject line.

Background

Designated standards are specific standards that have been officially recognised by regulatory authorities in the UK as providing a presumption of conformity with the essential requirements of relevant regulations.

In the context of devices, these standards are designated by the MHRA. These standards are published on Designated standards.

When a device complies with a designated standard, the device meets relevant essential requirements the standard addresses.

Data Privacy Statement

This survey seeks the views of individuals to inform MHRA's understanding of how designated standards are used in the UK to provide a presumption of conformity with the essential requirements of the MDR 2002.

This notice sets out how data collected through this survey will be used and respondents' rights under Articles 13 and/or 14 the UK General Data Protection Regulation (GDPR). Further information can be found at Medicines and Healthcare products Regulatory Agency privacy notice - GOV.UK.

Data controller

The Medicines and Healthcare products Regulatory Agency (MHRA) is the data controller.

What personal data we collect

You can respond to this survey online. Alternatively, you can download the form, complete it and send this to us by email at info@mhra.gov.uk with the subject line "Designated Standards Survey".

We will collect data on:

- whether you are responding on behalf of an organisation
- what organisation you are responding on behalf of (if any)
- the name of your organisation
- the country and region your organisation provides services in the UK (if any)

With your consent, we will also collect data on:

- your email address (if completing a paper survey and submitting it by email, or if you have confirmed the MHRA can contact you about your response); and
- any other personal data you volunteer by way of evidence or example in your response to open-ended questions in the survey; therefore, to remain anonymous, please refrain from disclosing any personally identifiable information in these questions.

How we use your data (purposes)

Your data will be treated in the strictest of confidence. We collect your personal data as part of the survey process:

- for statistical purposes, for example, to understand how representative the results are and whether views and experiences vary across demographics.
- so that MHRA can contact you for further information about your response (if you have given your consent).

Legal basis for processing personal data

The legal basis for processing your personal data is to perform a task carried out in the public interest, or in the exercise of official authority vested in the controller.

Data processors and other recipients of personal data

All responses to the survey will be seen by:

- Professionals within the MHRA who are working on this survey and policy area
- MHRA's third-party supplier (SocialOptic), who is responsible for running and hosting the online survey

No personally identifiable data will be shared.

The MHRA may also share your responses, when anonymised, with Department of Health and Social Care, Government Legal Department, Office for Life Sciences, and any other government body identified to be part of this survey.

International data transfers and storage locations

Storage of data by the MHRA is provided via secure computing infrastructure on servers located in the UK. Our platforms are subject to extensive security protections and encryption measures. Storage of data by SurveyOptic is provided via secure servers located in the United Kingdom (UK).

Retention and disposal policy

Personal data will be held by the MHRA for 3 years and disposed of sooner if possible. SurveyOptic will securely erase the data held on their system 5 years after the online survey closes, or when instructed to do so by the MHRA if the data has served its intended purpose (whichever happens earlier). Data retention will be reviewed on an annual basis. Anonymised data may be kept indefinitely.

How we keep your data secure

The MHRA uses appropriate technical, organisational and administrative security measures to protect any information we hold in our records from loss, misuse, unauthorised access, disclosure, alteration and destruction. We have written procedures and policies which are regularly audited and reviewed at a senior level. SurveyOptic is Cyber Essentials certified.

Your rights as a data subject

By law, you have rights as a data subject. Your rights under the UK General Data Protection Regulation and the UK Data Protection Act 2018 apply.

These rights are:

- the right to get copies of information – individuals have the right to ask for a copy of any information about them that is used;
- the right to get information corrected – individuals have the right to ask for any information held about them that they think is inaccurate, to be corrected;
- the right to limit how the information is used – individuals have the right to ask for any of the information held about them to be restricted, for example, if they think inaccurate information is being used;

- the right to object to the information being used – individuals can ask for any information held about them to not be used. However, this is not an absolute right, and continued use of the information may be necessary, with individuals being advised if this is the case; and
- the right to get information deleted – this is not an absolute right, and continued use of the information may be necessary, with individuals being advised if this is the case.

Comments or complaints

Anyone unhappy or wishing to complain about how personal data is used as part of this programme, should contact dataprotection@mhra.gov.uk in the first instance or write to:

Data Protection Officer

MHRA

10 South Colonnade

London

E14 4PU

Anyone who is still not satisfied can complain to the Information Commissioner's Office.

Their website address is www.ico.org.uk and their postal address is:

Information Commissioner's Office

Wycliffe House

Water Lane

Wilmslow

Cheshire

SK9 5AF

Definitions

For the purpose of this survey, the following definition applies:

Device

A fuller definition of medical device is contained in Regulation 2 of the Medical Devices Regulations 2002 (MDR 2002).

The term device encompasses a range of different types of medical devices and IVD devices used for the diagnosis, prevention, monitoring and treatment of disease, injury, or disability, including:

1. general medical devices
2. software as a medical device (including AI as a medical device)
3. implantable devices (including active implantable devices) – those medical devices intended to be totally or partially introduced into the human body and remain in the human body.
4. system and procedure packs – combinations of products that are packaged together and intended to be used for a specific medical purpose
5. medical devices with a sterile aspect
6. invasive medical devices
7. non-invasive medical devices
8. devices that are composed of substances
9. devices that administer substances or medicines
10. devices for disinfecting/cleaning
11. in vitro diagnostic devices (IVDs) - used for the in vitro (outside of a living organism) examination of specimens from the human body
12. accessory to a medical device - an article which, whilst not being a medical device, is intended specifically by its manufacturer to be used together with a medical device to enable it to be used

Section 1: About you

This section aims to gather information about your role, the nature of your organisation, the types of devices you deal with, and your organisation's size and market reach. This information will help us understand the landscape of device manufacturing and supply in Great Britain.

Which best applies to you:

- ○ I am responding as an individual
- ○ I am responding on behalf of an organisation

Which of the following best describes you or the organisation you work for?

- ○ A manufacturer
- ○ A UK Responsible Person (UKRP)
- ○ A UK Approved Body
- ○ A Healthcare professional
- ○ A user of devices
- ○ Other

Do you or your organisation manufacture or supply devices?

- ○ Yes
- ○ No

Which markets do you supply? Please select all that apply.

- ☐ Great Britain (England, Scotland, and Wales)
- ☐ Northern Ireland
- ☐ Other

For the devices your organisation manufactures and/or supplies to Great Britain, which is the predominant type of device?

- [ ] General medical devices (excluding software and implantable devices)
- [ ] Active implantable medical devices (therapeutic/diagnostic/administering)
- [ ] Software medical devices (including AI as a medical device)
- [ ] Implantable medical devices
- [ ] Medical devices with a measuring function
- [ ] Medical devices with a sterile aspect
- [ ] Invasive medical devices
- [ ] Non-invasive medical devices
- [ ] Devices that are composed of substances
- [ ] Devices that administer substances or medicines
- [ ] Devices for disinfecting/cleaning
- [ ] IVD devices
- [ ] Systems and procedure packs
- [ ] Surgical instruments
- [ ] Accessory to a medical device
- [ ] Dont know
- [ ] Other

For the devices your organisation manufactures and/or supplies to Great Britain, what is the predominant product marking(s) on the devices?

- ( ) UKCA only
- ( ) UKCA and CE marked
- ( ) Other

For the devices your organisation manufactures and/or supplies to Great Britain, what is the current MDR 2002 classification of the predominant type of devices?

- [ ] Class I
- [ ] Class IIa
- [ ] Class IIb
- [ ] Class III
- [ ] Annex II List A IVD
- [ ] Annex II List B IVD
- [ ] Self-test IVD
- [ ] General IVD

Within the UK, is your organisation classified as a micro, small, medium, or large employer? If you are unsure, you may select up to two categories you consider your organisation may most likely fall within.

- [ ] Micro-sized business: a business with 0 to 9 employees
- [ ] Small-sized business: a business with 10 to 49 employees
- [ ] Medium-sized business: a business with 50 to 249 employees
- [ ] Large business: a business with 250 or more employees

Choose no more than 2.

Would you be happy for us to contact you to follow up on your responses or address any further questions?

- ( ) Yes
- ( ) No

If yes, please provide your email address. With your consent, we shall use the email address provided to address any further questions, if necessary.

Section 2: Designated standards use in Great Britain

This section gathers information on the standards your organisation uses, their frequency of use and importance. This information will inform the MHRA in understanding compliance practices and identifying key standards used.

Does your organisation currently use any standards that are already designated for compliance with the essential requirements of MDR 2002 and place devices on the GB market?

- ○ Yes
- ○ No

Which standards that are already designated do you or your organisation use most frequently for compliance with the essential requirements of the MDR 2002 and place devices on the GB market? Please list all standards that apply.

Which standards that are already designated do you or your organisation consider are most important for compliance with the essential requirements of the MDR 2002 and place devices on the GB market? Please list all standards that apply.

Section 3: Designated standards lists

This section gathers inputs on the already designated standards lists. This information will help the MHRA in understanding the standards used for which new designation, update, removal or replacement would be considered.

When considering the already designated standards list, are there any standards that you consider should be added?

- ○ Yes
- ○ No

Please list all the standards you consider should be added to the designated standards list. There is the option below to upload a document.

Option to upload a list of all the standards you consider should be added to the designated standards list. (optional)

Upload a file

Choose File No file chosen

When considering the already designated standards list, are there any standards that you consider should be removed? This could include standards that no longer apply.

- Yes
- No

Please list all the standards you consider should be removed from the designated standards list. There is the option below to upload a document.

Option to upload a list of all the standards you consider should be removed from the designated standards list. (optional)

Upload a file

Choose File No file chosen

When considering the already designated standards list, are there any standards that you consider should be replaced? This could include standards that need to be changed to alternative standards.

- ○ Yes
- ○ No

Please list all the standards you consider should be replaced on the designated standards list and where applicable include the replacement standard. There is the option below to upload a document.

Option to upload a list of all the standards you consider should be replaced on the designated standards list and where applicable include the replacement standard. (optional)

Upload a file

Choose File No file chosen

When considering the already designated standards list, are there any standards that you consider should be updated? This could include standards that have since been superseded by newer standards.

- ○ Yes
- ○ No

Please list all the standards you consider should be updated on the designated standards list. There is the option below to upload a document.

Option to upload a list all the standards you consider should be updated on the designated standards list. (optional)

Upload a file

Choose File No file chosen

We are interested to hear about how useful the designated standards are for compliance with the essential requirements and market access for devices in GB.

For each of the statements below, please could you indicate to what extent you agree/ disagree with the statement.

The use of a designated standard and the presumption of conformity it provides, saves our organisation time in the submission and approval process for devices to be placed on the GB market.

- ○ Strongly disagree
- ○ Disagree
- ○ Neither agree or disagree
- ○ Agree
- ○ Strongly agree

The use of designated standards to demonstrate compliance to the essential requirements under the MDR 2002 is helpful for our business compliance and efficiency.

- ○ Strongly disagree
- ○ Disagree
- ○ Neither agree or disagree
- ○ Agree
- ○ Strongly agree

Designated standards that contain mapping to the essential requirements are useful to ensure our devices meet relevant requirements to be placed on the Great Britain market.

- ○ Strongly disagree
- ○ Disagree
- ○ Neither agree or disagree
- ○ Agree
- ○ Strongly agree

Review your answers

Please use this opportunity to review your response. If you wish to make any amends you can do so by clicking on the "change" link next to the answer given. This will return you to the relevant page to amend your answer.

Information for respondents

Background

Data Privacy Statement

Definitions

Section 1: About you

Which best applies to you:	Unanswered	Change
Which of the following best describes you or the organisation you work for?	Unanswered	Change

Do you or your organisation manufacture or supply devices?	Unanswered	Change
Which markets do you supply? Please select all that apply.	Unanswered	Change
For the devices your organisation manufactures and/or supplies to Great Britain, which is the predominant type of device?	Unanswered	Change
For the devices your organisation manufactures and/or supplies to Great Britain, what is the predominant product marking(s) on the devices?	Unanswered	Change
For the devices your organisation manufactures and/or supplies to Great Britain, what is the current MDR 2002 classification of the predominant type of devices?	Unanswered	Change
Within the UK, is your organisation classified as a micro, small, medium, or large employer? If you are unsure, you may select up to two categories you consider your organisation may most likely fall within.	Unanswered	Change
Would you be happy for us to contact you to follow up on your responses or address any further questions?	Unanswered	Change

If yes, please provide your email address. With your consent, we shall use the email address provided to address any further questions, if necessary.	Unanswered	Change

Section 2: Designated standards use in Great Britain

Does your organisation currently use any standards that are already designated for compliance with the essential requirements of MDR 2002 and place devices on the GB market?	Unanswered	Change
Which standards that are already designated do you or your organisation use most frequently for compliance with the essential requirements of the MDR 2002 and place devices on the GB market? Please list all standards that apply.	Unanswered	Change

Which standards that are already designated do you or your organisation consider are most important for compliance with the essential requirements of the MDR 2002 and place devices on the GB market? Please list all standards that apply.	Unanswered	Change

Section 3: Designated standards lists

When considering the already designated standards list, are there any standards that you consider should be added?	Unanswered	Change
Please list all the standards you consider should be added to the designated standards list. There is the option below to upload a document.	Unanswered	Change
Option to upload a list of all the standards you consider should be added to the designated standards list.	Unanswered	Change
When considering the already designated standards list, are there any standards that you consider should be removed? This could include standards that no longer apply.	Unanswered	Change

Please list all the standards you consider should be removed from the designated standards list. There is the option below to upload a document.	Unanswered	Change
Option to upload a list of all the standards you consider should be removed from the designated standards list.	Unanswered	Change
When considering the already designated standards list, are there any standards that you consider should be replaced? This could include standards that need to be changed to alternative standards.	Unanswered	Change
Please list all the standards you consider should be replaced on the designated standards list and where applicable include the replacement standard. There is the option below to upload a document.	Unanswered	Change
Option to upload a list of all the standards you consider should be replaced on the designated standards list and where applicable include the replacement standard.	Unanswered	Change

When considering the already designated standards list, are there any standards that you consider should be updated? This could include standards that have since been superseded by newer standards.	Unanswered	Change
Please list all the standards you consider should be updated on the designated standards list. There is the option below to upload a document.	Unanswered	Change
Option to upload a list all the standards you consider should be updated on the designated standards list.	Unanswered	Change
The use of a designated standard and the presumption of conformity it provides, saves our organisation time in the submission and approval process for devices to be placed on the GB market.	Unanswered	Change
The use of designated standards to demonstrate compliance to the essential requirements under the MDR 2002 is helpful for our business compliance and efficiency.	Unanswered	Change

Designated standards that contain mapping to the essential requirements are useful to ensure our devices meet relevant requirements to be placed on the Great Britain market.	Unanswered	Change

Ready for submission

You have now come to the end of the survey. By clicking on the [Submit] button you will submit your response. You will not receive a copy of your response.

There will be no opportunity to edit your response once it is submitted. If you wish to make any further amends, please return to the review page by clicking [Back].

Thank you for participating in this survey. Your input is greatly appreciated and will play a valuable role in supporting our approach to the prioritisation of standards for designation.

This survey is now closed.