



Medicines & Healthcare products
Regulatory Agency

Questionnaire on the Impacts of The Medical Devices (Amendment) Regulations 2026

Questions guidance

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Executive Summary

This document provides guidance for completing the “Questionnaire on the Impacts of The Medical Devices (Amendment) Regulations 2026,” issued by the Medicines and Healthcare products Regulatory Agency (MHRA). These regulations are referred to as “the 2026 Regulations” throughout this document. It aims to gather data from manufacturers, healthcare organisations, approved bodies, UK Responsible Persons, patients and other stakeholders on the costs, benefits, and impacts of the proposed regulatory changes. The 2026 Regulations are designed to strengthen patient safety, support innovation, and align Great Britain’s medical device framework with international best practices. The questionnaire seeks input on anticipated economic, operational, equality and compliance implications of the updated regulations. Responses will inform the MHRA’s impact assessment and help shape the final regulatory framework.

Document Purpose

This document is a detailed guidance and reference manual for stakeholders completing the 2026 Regulations Impact Questionnaire. It explains the background of the MHRA’s regulatory reforms, outlines the scope and key topics covered by the new regulations, and provides instructions for accurately completing each section of the questionnaire. The document helps ensure that responses are consistent, comprehensive, and based on informed understanding, thereby enabling the MHRA to collect high-quality data for its impact assessment. Your responses will help us develop a balanced and evidence-based regulatory framework that enhances safety while fostering innovation in medical technologies across Great Britain.

Introduction

This questionnaire aims to gather data on the costs and benefits of [The Medical Devices \(Amendment\) Regulations 2026](#) (“the 2026 Regulations”), which are provisions that strengthen safe access to medical devices and *in vitro* diagnostic (IVD) devices in Great Britain (GB) (England, Scotland, and Wales) as well as enable greater innovation of MedTech. Your participation will help the MHRA understand the impact of the proposed changes.

Participation in this survey is your opportunity to share the impact these regulations will have on you or your operations. The survey explores the financial implications of all topics covered in the 2026 Regulations, allowing you to highlight any economic challenges that you may encounter. Your inputs will therefore contribute to a more comprehensive understanding of the business impacts of the 2026 Regulations.

This questionnaire will be distributed to various stakeholders. With the appropriate information at hand, **it is estimated that the questionnaire will take approximately:**

- **45 minutes for Manufacturers**
- **20 minutes for Healthcare Organisations**
- **20 minutes for Approved Bodies**
- **20 minutes for UK Responsible Persons (UKRPs)**
- **15 minutes for patients or carers**

All respondents should read the first section of this guidance, specifically sections 1 to 7. Further down, there is guidance that is specific to the type of respondent.

This questionnaire will be open from Monday 11th May 2026 to Friday 19th June.

Information for all respondents

1. Background to MHRA and medical device regulation

The MHRA regulates medicines, medical devices and blood components for transfusion in the UK. Acting on behalf of the Secretary of State for Health and Social Care, the MHRA is the designated competent authority that regulates compliance with and enforces the law on medical devices in the UK.

This includes overseeing the implementation of the Medical Device Regulations (SI 2002, No 618, as amended) (MDR 2002). These regulations cover the safety and performance requirements that medical devices, *in vitro* diagnostic medical devices (IVD devices), and their accessories must meet before being placed on the Great Britain (GB) market, and the rules for ongoing safety and performance monitoring of these products once they are on the market.

The MHRA is undertaking an extensive reform of medical devices regulations. The regulatory framework has not kept pace with advancements and is no longer aligned with international best practices. Reform is needed to strengthen patient safety, ensure rapid access to products, and support innovation by modernising the regulations.

As described in the [Roadmap](#) towards the future regulatory framework for medical devices, published in December 2024, the MHRA is taking a phased approach to amending the MDR 2002 through secondary legislation. Since the Roadmap's publication:

- The Medical Devices ([Post-market Surveillance Requirements](#)) (Amendment) (Great Britain) Regulations 2024 came into force in June 2025.
- The MHRA has published regulations in a draft statutory instrument for the future regime, referred to in this document as 'The Medical Devices (Amendment) Regulations 2026' (the "2026 Regulations").

This questionnaire specifically asks about the impacts of the 2026 Regulations.

The scope section of this guidance outlines the policies included in the 2026 Regulations, drawing from the following key consultations:

- [2021 Consultation on the future regulation of medical devices in the United Kingdom](#)
- [2024-25 Consultation on Medical Devices Regulations: Routes to market and in vitro diagnostic devices](#)
- [2024 Consultation on common specification requirements for in vitro diagnostic devices](#)

2. What is this questionnaire for?

This questionnaire gathers data on the costs and benefits of the 2026 Regulations. The collected data will be weighted and averaged to estimate the likely impacts of these proposals on affected partners. This information will be input to the impact assessment for the proposed regulatory updates, helping the MHRA understand the costs and benefits of the proposed changes.

If the impact assessment is published¹, the data collected through this questionnaire will be anonymised.

Your response will be essential in helping the MHRA develop a comprehensive understanding of the impacts of the proposed changes to the MDR 2002.

3. How does this questionnaire differ from the April 2024 questionnaire?

In 2021, the MHRA consulted on a wide range of proposed changes to the regulations for medical devices in the UK. The consultation consisted of 15 chapters, with a range of proposals on different aspects of the regulations.

In June 2022, the government published its [response](#), setting out significant legislative changes.

In April 2024, the MHRA launched a business questionnaire to gather information on the impacts on businesses of future regulations for medical devices. The questionnaire covered all topics from the government's response except post-market surveillance (PMS), transitional arrangements and certain Northern Ireland-specific measures, which were addressed in separate legislation

This new questionnaire is focused on supporting the specific proposals about routes to market and in vitro diagnostic devices, set out in the 2026 Regulations.

We are inviting organisations that responded in April 2024 to share their views again, and we also want input from manufacturers, Approved Bodies, healthcare organisations, UK Responsible Persons (UKRPs), and patients.

Your feedback will help shape the future regulatory framework for medical devices in the UK.
Your voice matters - please take part.

¹ The [Better Regulation Framework guidance](#) provides the conditions when an impact assessment must be published. The conditions state where regulatory measures have an expected annual net direct cost or benefit (EANDCB) to businesses of more than £10m a year, it must be published.

4. What is the scope of the new regulations?

The MHRA intends to update the regulatory framework by laying legislation concerning:

- Definitions used in the legislation
- Classifications
- Essential requirements
- Technical documentation retention periods
- Equivalence
- Implant cards
- Custom-made devices
- Claims
- Software as a Medical Device
- *In vitro* diagnostic (IVDs) devices
- International reliance
- Unique Device Identifiers
- Electronic instructions for use

[Annex A](#) provides a short description of each of these areas.

When completing the questionnaire please refer to the information stated in the [2026 Regulations](#) as outlined below. Please note that, in some cases, information relating to a single topic is distributed across multiple sections of the 2026 Regulations. Where this occurs, we have provided the primary page references only, rather than an exhaustive list of all relevant pages:

- Definitions used in the legislation (pages 3-5, 13, 26, and 35-36)
- Classifications (general medical devices and active implantable medical devices: pages 91-100, IVD devices: pages 100-104)
- Essential requirements (general medical devices and active implantable medical devices: pages 71-74, IVD devices: pages 76-77)
- Technical documentation retention periods (pages 16-17, 29 to 30, 39-40, 74-75, and 78)
- Equivalence (pages 18-19, and 31-32)
- Implant cards (pages 24-25, and 34-35)
- Custom-made devices (pages 13, 14, 21-22, 26, 28, and 32-33)
- Claims (pages 24, 33-34, and 44-45)
- Software as a Medical Device (pages 13, 19-20, 22-23, 25 to 26, 36, 41-43, and 45)
- *In vitro* diagnostic (IVD) devices (please see above references, and also pages 35-45)
- International reliance (pages 51-62)
- Unique Device Identifiers (pages 79-87)
- Electronic instructions for use (pages 87-91)

5. Confidentiality and data protection

This section sets out how data collected through this survey will be used and respondents' rights under Articles 13 and/or 14 of 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.

We will collect data on:

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

With your consent, we will also collect data on:

- your email address; 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 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

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 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.

You can find further information on MHRA Privacy Notice [here](#).

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6.Guidance on completing the questionnaire

Your responses should focus on the additional impacts that the new/proposed 2026 Regulations for medical devices will have. Do not include impacts from any other legislation.

When questions ask for the "additional" costs, benefits, or impacts of a particular measure, this means additional compared to the scenario where the 2026 Regulations are not implemented. You are not required to provide evidence for your response, although you may do so in the comments section at the end of the questionnaire. Many questions concern your perception of how the legislation will impact you or your organisation.

Respondents should provide their best available estimates. If you are uncertain, you may provide ranges or multiple answers. Many questions ask for a best available estimate from a range of tick-box responses. Respondents can select multiple responses if they are unsure where their best estimate lies. For example, in the following hypothetical question:

“In the most recent year for which you have data, which of the following categories best reflects your organisation's turnover from activities within the UK?”

- a) £0 – £0.99m
- b) £1m – £4.99m
- c) £5m – £9.99m
- d) £10m – £24.99m
- e) £25m – £49.99m
- f) £50m – £99.99 m
- g) £100m – £249.99m
- h) £250m – £499.99m
- i) £500m – £999.99m
- j) £1bn +

If you are unsure which option best fits, and your organisation's turnover falls between £1 million and £9.99 million, please select both the “£1 million – £4.99 million” and “£5 million – £9.99 million” options.

7.Navigating this questionnaire

This questionnaire is hosted on the SurveyOptics platform. Use the 'Next Page' and 'Previous Page' buttons to move through the questionnaire. Do not use the back button on your browser to go to previous page or you will lose all your data.

You do not need to complete the survey in one sitting. There is an option to save your responses and continue at a later point. The questionnaire tailors the question set according to respondents' answers. Consequently, the questionnaire will present different sets of questions depending on the type of respondent and answers given to previous questions. The first question in the questionnaire is:

Which of the following best describes you or the organisation you work for? If more than one option applies, please select the one that is most relevant. If you wish to reflect multiple roles, please complete separate entries for the survey.

- a) A manufacturer
- b) A Healthcare Organisation
- c) An Approved Body
- d) A UK Responsible Person (UKRP)
- e) A patient or carer
- f) Other, please specify

Your answer to this first question will determine the subsequent questions you will get. Therefore, it is important that you answer this question correctly.

The next part of guidance is specific to what your answer would be to this question.

Please click [here](#) for the specific guidance if you are a Manufacturer (page 21).

Please click [here](#) for the specific guidance if you are a Healthcare Organisation (page 31).

Please click [here](#) for the specific guidance if you are an Approved Body (page 38).

Please click [here](#) for the specific guidance if you are a UKRP (page 45).

Please click [here](#) for the specific guidance if you are a patient or carer (page 50).

Please click [here](#) for the specific guidance for if you selected 'Other, please specify' (page 54).

However, the [frequently asked questions section](#), [Annex A](#), [Annex B](#) and [Annex C](#) are applicable for all respondents.

Questions and Guidance

Questions for manufacturers

This questionnaire is intended for manufacturers, healthcare organisations, Approved Bodies, UK Responsible Persons, patients and other organisations that may be impacted by The Medical Devices (Amendment) Regulations 2026 (“the 2026 Regulations”). The MHRA aims to gather data on the costs and benefits of the 2026 Regulations that will introduce strengthened pre-market measures for medical devices in Great Britain (GB) (England, Scotland, and Wales).

Your participation will help the MHRA understand the impact of the proposed changes. The survey explores the financial implications of all topics covered in the 2026 Regulations, allowing you to highlight any economic impacts you face.

Where possible, this questionnaire should be completed by the individual(s) responsible for the relevant question area within the organisation. **Responses should represent the organisation as a whole.**

It is estimated that the questionnaire will take approximately 45 minutes for manufacturers.

The questionnaire follows three parts:

1. Background and your organisation
2. Questions on the 2026 Regulations
3. Feedback

Background and your organisation

1. Which of the following best describes you or the organisation you work for? If more than one option applies, please select the one that is most relevant. If you wish to reflect multiple roles, please complete separate entries for the survey.

- a) A manufacturer
- b) A Healthcare Organisation
- c) An Approved Body
- d) A UK Responsible Person (UKRP)
- e) A patient or carer
- f) Other, please specify
(Open text box)

2. What is the full legal name of your organisation?
(Open text box)

3. What is your legal manufacturing address?
(Open text box)

4. Which markets do you supply? You can select multiple options.
 - a) Great Britain
 - b) Northern Ireland
 - c) EU and/or EEA countries
 - d) United States
 - c) Rest of the world

5. What types of device does your organisation supply to the GB market? You can select multiple options.
 - a) General Medical Devices
 - b) IVD device and kits
 - c) Implantable devices
 - d) Software as a Medical Device
 - e) AI as a Medical Device
 - f) Custom made devices
 - g) Systems and procedure packs
 - h) Dental appliances
 - i) Surgical instruments
 - j) N/A
 - k) Other, please specify
(Open text box)

6. Of the medical devices / IVD devices you manufacture and/or supply to Great Britain, are these mostly:
 - a) UKCA only
 - b) CE only
 - c) Both UKCA and CE marked

7. Of the medical devices / IVD devices that you supply to GB, approximately what proportion are UKCA marked (i.e., are either UKCA marked only or are dual UKCA and CE marked)? (please enter a percentage e.g. if a quarter are UKCA marked, enter 25%)
(Open text box)

8. Of the medical devices / IVD devices that you supply to GB, approximately what proportion are CE marked only? (please enter a percentage, e.g. 40%)
(Open text box)

9. Are the devices you manufacture and / or supply to the GB market mostly: (You can select multiple options.)
 - a) Class I
 - b) Class IIa
 - c) Class IIb
 - d) Class III
 - e) General IVD
 - f) Self-test IVD
 - g) List A IVD
 - h) List B IVD
 - i) EU IVDR Class A
 - j) EU IVDR Class B
 - k) EU IVDR Class C

I) EU IVDR Class D

10. If you are based outside the UK, how many UK Responsible Persons (UKRPs) do you have?

(Dropdown: 1, 2, 3, 4, N/A etc.)

11. The 2026 Regulations require a physical presence in the UK. If you are a manufacturer based outside the UK, is your UK Responsible Person (UKRP) physically located at an address within the UK?

- a) Yes
- b) No

12. Within the UK, is your organisation classified as a micro, small, medium, or large employer?

- 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

- a) Micro
- b) Small
- c) Medium
- d) Large

13. What is the most recent year for which you have data on your organisation's turnover from activities within the UK related to manufacturing medical devices?

- a) April 2024 to March 2025
- b) April 2023 to March 2024
- c) April 2022 to March 2023
- d) April 2021 to March 2022
- e) April 2020 to March 2021
- f) Other, please specify
(Open text box)

14. For the most recent year you have data, which of the following best describes your organisation's UK turnover from manufacturing medical devices?

- a) £0 – £0.99 m
- b) £1 m – £4.99 m
- c) £5 m – £9.99 m
- d) £10 m – £24.99 m
- e) £25 m – £49.99 m
- f) £50 m – £99.99 m
- g) £100 m – £249.99 m
- h) £250 m – £499.99 m
- i) £500 m – £999.99
- j) Other, please specify
(Open text box)

Questions on the 2026 Regulations

15. Have you started incurring costs due to regulatory requirements in countries or jurisdictions outside GB (e.g., from transitioning to EU regulations on medical devices and IVD devices)?
- a) Yes
 - b) No
 - c) Unsure
16. If you answered 'yes' to question 15, please estimate the costs (to the nearest £ '000s) that you have incurred and outline international regulations that have generated these costs.
(Open text box)

The following questions will relate to your estimated additional setup and ongoing annual costs arising from the 2026 Regulations.

17. Assuming conformity assessment costs by conformity assessment bodies (e.g. approved bodies) stay the same, what additional **one-off or setup** costs do you expect your organisation to face once the 2026 Regulations are fully implemented? If unsure, please provide an estimated range (e.g. "£25k-£50k"). Specify the broad categories that are required for one-off or setup costs.
(Open text box)
18. Of these additional one-off or set-up costs, what proportion can be attributed to each of the following areas? Please ensure that percentages total to 100%.
- Definitions used in the legislation
 - Classifications
 - Essential requirements
 - Technical documentation retention periods
 - Equivalence
 - Implant cards
 - Custom-made devices
 - Claims
 - Software as a Medical Device
 - *In vitro* diagnostic (IVDs) devices
 - International reliance
 - Unique Device Identifiers
 - Electronic instructions for use
- (Open text box)
19. If you cannot give a cost estimate breakdown (to the nearest £ '000s) for question 18, please select the areas where you expect to see the highest additional set-up costs.
- Definitions used in the legislation

- Classifications
- Essential requirements
- Technical documentation retention periods
- Equivalence
- Implant cards
- Custom-made devices
- Claims
- Software as a Medical Device
- *In vitro* diagnostic (IVDs) devices
- International reliance
- Unique Device Identifiers
- Electronic instructions for use

20. Assuming conformity assessment costs by conformity assessment bodies (e.g. approved bodies) stay the same, what additional annual or ongoing costs do you expect after implementation of the 2026 Regulations? If unsure, please provide an estimated range (e.g. “£25km–£50k”). Please share a reason for your cost estimate.
(Open text box)

21. Of these additional **ongoing or annual costs**, what proportion can be attributed to each of the following areas? Please ensure that percentages total to 100%.

- Definitions used in the legislation
 - Classifications
 - Essential requirements
 - Technical documentation retention periods
 - Equivalence
 - Implant cards
 - Custom-made devices
 - Claims
 - Software as a Medical Device
 - *In vitro* diagnostic (IVDs) devices
 - International reliance
 - Unique Device Identifiers
 - Electronic instructions for use
- (Open text box)

22. If you can't give a cost breakdown for question 21, please select the areas where you expect to see the highest additional ongoing or annual costs.

- Definitions used in the legislation
- Classifications
- Essential requirements
- Technical documentation retention periods
- Equivalence
- Implant cards
- Custom-made devices
- Claims
- Software as a Medical Device
- *In vitro* diagnostic (IVDs) devices
- International reliance

- Unique Device Identifiers
- Electronic instructions for use

The following questions will relate to actions your organisation may take in response to the 2026 Regulations.

23. As a result of the measures in the 2026 Regulations, what percentage change in the number of medical device models supplied by your organisation to GB do you anticipate 10 years after implementation? (e.g. -10% (i.e. reduction) or +10% (i.e. increase))
(Open text box)
24. What are the main reasons for the expected change in your organisation's medical device supply to GB over the next 10 years? (Please select all that apply)
- a) Full withdrawal of products from the GB market
 - b) Rationalisation of product offerings (e.g., fewer pack sizes or variants)
 - c) Regulatory burden or cost are too high
 - d) Switching to CE Marking
 - e) Switching to international reliance routes
 - f) No change, I will continue supply with no major changes
 - g) Alternative non-regulatory routes to market (e.g. research use)
 - h) Other (please specify)
(Open text box)
25. Do you anticipate an increase or decrease in the price of your products due to the 2026 Regulations?
- a) Increase
 - b) Decrease
 - c) No change
 - d) Unsure
26. What percentage change in your product price do you expect due to the 2026 Regulations? (e.g. -10% (i.e. reduction) or +10% (i.e. increase). If you are unsure, please enter a range. Please note, your response is kept confidential.)
(Open text box)

The following questions apply only to IVD manufacturers. If you do not manufacture IVDs, you may skip these questions.

27. (For IVD manufacturers only) What would be your predominant devices' new IVD classification as a result of the proposed IVD classifications changes?
- a) UK Class A
 - b) UK Class B
 - c) UK Class C

- d) UK Class D
- e) N/A (I do not make IVD devices)

28. *(For IVD manufacturers only)* What would be the costs as a result of the IVD classification changes and conformity assessment route changes? If you are unsure, please provide an estimated range (e.g., £25k- £50k). Specify the broad categories that are required for costs. If you do not manufacture IVDs, you may enter “N/A.”
(Open text box)
29. *(For IVD manufacturers only)* What would be the cost-savings as a result of the IVD classification changes and conformity assessment route changes? If you are unsure, please provide an estimated range (e.g., £25k- £50k). Specify the broad categories that are required for cost-savings. If you do not manufacture IVDs, you may enter “N/A.”
(Open text box)
30. *(For IVD manufacturers only)* If [common specifications](#) are applied to your Class D IVD device, what is the estimated cost increase you anticipate for compliance? If you do not manufacture IVDs, you may enter “N/A.”
(Open text box)

The following questions relate to international reliance as described in the 2026 Regulations.

31. Which international reliance route(s) do you intend to use?
a) Route 1
b) Route 2
c) Route 3
d) N/A
32. Why do you intend to use this route(s)? Please provide a brief explanation, or “N/A” if not using.
(Open text box)
33. What is your expected cost-saving (if any) if the proposed Route 1 regulations are fully implemented? If you are unsure, please provide an estimated range (e.g., £25k–£50k). If not using this route, you may enter “N/A.”
(Open text box)
34. What is your expected increase (if any) in supply to GB if the proposed Route 1 regulations are fully implemented? If you are unsure, please provide an estimated range (e.g., 5–10%). If not using this route, you may enter “N/A.”
(Open text box)
35. What is your expected cost-saving (if any) if the proposed Route 2 regulations are fully implemented? If you are unsure, please provide an estimated range (e.g., £25k–£50k). If not using this route, you may enter “N/A.”
(Open text box)

36. What is your expected increase (if any) in supply to GB if the proposed Route 2 regulations are fully implemented? If you are unsure, please provide an estimated range (e.g., 5–10%). If not using this route, you may enter “N/A.”
(Open text box)
37. What is your expected cost-saving (if any) if the proposed Route 3 regulations are fully implemented? If you are unsure, please provide an estimated range (e.g., £25k–£50k). If not using this route, you may enter “N/A.” Specify the broad categories of cost-savings.
(Open text box)
38. What is your expected increase (if any) in supply to GB if the proposed Route 3 regulations are fully implemented? If you are unsure, please provide an estimated range (e.g., 5–10%). If not using this route, you may enter “N/A.”
(Open text box)

The following questions relate the overall impact of the 2026 Regulations.

39. Do you believe that the 2026 Regulations will encourage innovation?

“Innovation in healthcare is the process of introducing new ideas, methods, technologies, products, or services aimed at improving healthcare delivery, patient outcomes, and overall efficiency within the healthcare providers (e.g. NHS). It includes the creation and implementation of concepts, ideas, technologies, processes, and services that benefit clinical outcomes and enhance patient experiences.”

- a) Yes
- b) No
- c) Unsure

40. Please explain your answer to the previous question: ‘do you believe that the 2026 Regulations will encourage innovation?’
(Open text box)

41. As a result of these regulations being implemented, do you think the proportion of adverse medical device incidents related to medical devices manufactured or supplied by your organisation will increase, decrease or stay the same?
- a) Increase
 - b) Decrease
 - c) Stay the same
 - d) I don’t know

42. What percentage change in the proportion of adverse medical device incidents related to medical devices manufactured or supplied by your organisation do you expect due to the 2026 Regulations? (e.g. -10% (i.e. reduction) or +10% (i.e. increase). If you are unsure, please enter a range.
(Open text box)

43. As a result of these regulations being implemented, do you think the proportion of adverse medical device incidents across Great Britain will increase, decrease or stay the same?
- a) Increase
 - b) Decrease
 - c) Stay the same
 - d) I don't know
44. What percentage change in the proportion of adverse medical device incidents across Great Britain do you expect due to the 2026 Regulations? (e.g. -10% (i.e. reduction) or +10% (i.e. increase). If you are unsure, please enter a range.
(Open text box)

End of questionnaire and feedback

45. Thank you very much for your feedback. Your responses are essential in ensuring the MHRA and the government understand the impacts of these proposed regulatory changes. If you have any other comments you wish to add, please do so below in 100 words or less.
(Open text box)

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.

Guidance on questions for manufacturers

- **Question 3:** A physical UK address refers to a location that is physically situated within the United Kingdom. This includes a specific place where a person or business can be contacted or where documents can be served. It must be a tangible location such as a house, flat, office, or any other physical structure. The address should not be a virtual office, shell company, forwarding office, or PO Box, as these do not represent a physical presence.
- **Question 12:** the definitions of micro, small, medium and large can be found below:
 - 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
- **Questions 12 and 14** are designed to determine how representative your firm is of the wider industry.
 - This data is used to extrapolate the impacts of the legislation to the broader industry, ensuring that all responses are representative. At no point in this questionnaire is any company-specific identifying feature requested, and all responses will be aggregated, so it will not be possible to identify your organisation from the response.
 - Respondents can provide multiple answers to indicate uncertainty. All UK companies are required to file accounts with [Companies House](#), so the turnover of the UK company will usually be retrievable from this website.
 - As always, respondents are only expected to provide their best available answer. Therefore, an informed estimate (or estimates) is preferable to no response.
- **Question 13:** this question has been included because providing the most recent year of available turnover information allows the turnover data to be adjusted to the current price level, accounting for inflation.
- **Question 15:** businesses have previously been asked about the additional costs of these regulations, with respondents instructed to ignore the costs of other questions when providing their answers. However, this question specifically asks businesses to reflect on whether any other international regulations have affected their operations. They should specify the costs incurred as a result of these regulations, such as compliance costs, administrative expenses, or changes in production processes. Respondents should also include which specific regulations they are referring to in their response.
- **Question 16:** businesses should consider how the regulations might incentivise or hinder innovation within their industry. They can provide examples of how similar regulations have impacted innovation in the past and discuss any potential benefits or challenges that the regulations might pose for their business's innovation efforts.

- **Question 17:** please provide your best available estimate. An informed estimate is preferable to no response. These costs are in addition to any costs your organisation may have already incurred (for example, from complying with EU MDR/EU IVDR). Respondents should be aware and take into consideration when providing their costs that there will be appropriate transition periods to ease the compliance burden for businesses. Additional information on the transition arrangements can be found in the 2026 Regulations. One-off or transition costs may include, but are not limited to:
 - Familiarisation and training of staff to understand new requirements
 - Administrative costs for upgrading equipment, IT systems, or facilities to meet new requirements
 - Administrative costs for hiring new staff

- **Questions 18 and 21:** these estimates will be used to inform which parts of the future regulations will have the greatest impact on businesses. Respondents should provide their best available estimate, or range of estimates, ensuring that percentages total to 100%. An informed estimate is preferable to no response. Please see below for an example response:
 - *Definitions used in the legislation – 3%*
 - *Classification – 3%*
 - *Essential requirements – 10%*
 - *Technical documentation retention periods – 5%*
 - *Equivalence – 10%*
 - *Implant cards – 10%*
 - *Custom-made devices – 5%*
 - *Claims – 10%*
 - *Software as a Medical Device – 10%*
 - *in vitro diagnostic (IVDs) devices – 10%*
 - *International reliance – 10%*
 - *Unique Device Identifiers– 10%*
 - *Electronic instructions for use – 4%”*
 - It is recognised that there may be overlap between some areas of the new requirements. However, respondents should provide their best estimate of accounting for the combined impact of these two interactions when responding.
 - The relevant pages in the 2026 Regulations for the sections can be found in the [Scope section](#) of the guidance and there is summary table of the proposed changes in [Annex A](#).
 - When ranking the areas, consider the following:
 - Familiarisation and Training: Costs associated with training staff to understand and comply with new regulations.
 - Administrative Costs: Costs related to upgrading equipment, IT systems, or facilities to meet new requirements.
 - Staffing Costs: Costs for hiring and maintaining additional staff to manage compliance.

- Ongoing Training: Costs for continuous training to keep staff updated with regulatory changes.
- **Questions 19 and 22** covers the same points as Questions 18 and 21 but do not require you to add proportions.
- **Question 20:** please provide your best available estimate. An informed estimate is preferable to no response. These costs are in addition to any costs your organisation may have already incurred or set up (for example, from complying with EU MDR/EU IVDR) and are also additional to the familiarisation costs noted in the previous question. Annual ongoing costs may include:
 - Costs of maintaining additional staff
 - Costs of maintaining new equipment or IT systems
 - Costs of maintaining new facilities
 - Costs of ongoing training
- **Question 23:** Reflect on your current supply levels as a baseline. Evaluate how the new regulations might affect your operations, including compliance costs and potential disruptions. Assess the anticipated demand for your medical devices in GB over the next decade, considering trends in healthcare needs and market dynamics. Think about any strategic adjustments your organisation might make in response to the regulations, such as expanding or reducing your product range. Based on these factors, estimate the percentage change in your medical device supply to GB, providing as specific an estimate as possible.

The percentage change in medical device supply refers to the changes in the number of different models supplied, rather than the number of units. For example, if your organisation supplied 20 different models of medical devices to the UK before the regulations and expects to supply 25-30 models after the regulations, this would be a 25% - 50% increase.

- **Question 26,** businesses should carefully consider how the new regulations might impact their production costs, supply chain, and overall business operations. Respondents can refer back to questions 15 and 17 from their previous answers on the costs of the 2026 Regulations. Respondents should then determine whether their organisation is likely to absorb these costs (i.e., not change their prices) or pass them on to consumers through higher prices. It may be helpful to review previous instances where production costs increased and analyse how the prices of medical devices changed as a result. Please provide a percentage indicating how much of the costs will be passed on to consumers.
- **Question 27:** To help work out the new IVD classification, please refer to the 2026 Regulations for more information on the classification system. However, for ease, a summary table is included in Annex C of this guidance.

- **Question 28:** To gain access to the GB market, depending on the classification of the IVD device, manufacturers must complete either a self-declaration or conformity assessment undertaken by a UK approved body, against a set of essential requirements. Therefore, to establish what regulatory requirements are needed to gain market access the IVD classification needs to be determined first. Once this is determined consider the potential reductions or increases in costs associated with each market access route. This may include savings from reduced regulatory assessments (for example, Class B IVD device are to be self-declared with QMS certification), and any other efficiencies gained. Think about the specific areas where costs might be reduced, such as administrative expenses, compliance costs, and time savings. If exact figures are not available, provide an estimated range based on your best judgment. A summary table of the regulatory requirements based on classification is included in Annex C of this guidance.
- **Question 29:** businesses should estimate the costs associated with meeting the common specifications, including testing, certification, and any necessary modifications to their device. They should consider both one-time and ongoing costs related to compliance
- **Questions 33, 35 and 37:** consider the potential reductions in costs associated with each International Reliance route. This may include savings from reduced duplication of regulatory assessments, streamlined processes, and any other efficiencies gained. Think about the specific areas where costs might be reduced, such as administrative expenses, compliance costs, and time savings. If exact figures are not available, provide an estimated range based on your best judgment. Please refer to the consultation for more information on each International Reliance route. However, for ease a summary table is included in [Annex B](#) of this guidance.
- **Questions 34, 36 and 38:** the MHRA is keen to understand your perception of the impact on the supply of medical devices in your organisation due to the implementation of each possible International Reliance route. Please estimate the potential increase in your supply chain capacity or production output if any as a result of the new regulations. Consider factors such as improved efficiency, reduced regulatory barriers, and enhanced market access. Provide your best available estimate or a range of estimates.

The percentage change in medical device supply refers to the changes in the number of different models supplied, rather than the number of units. For example, if your organisation supplied 20 different models of medical devices to the UK before the regulations and expects to supply 25-30 models after the regulations, this would be a 25% - 50% increase.

- **Question 41, 42, 43 and 44:** These regulations are designed to prevent potential risks and ensure that devices are safe and effective for their intended use. An adverse medical incident refers to any event that causes, or has the potential to cause, unexpected or

unwanted effects involving the safety of device users, including patients or other persons. An informed estimate is preferable to no response.

- **Question 45:** Please provide any insight on the impact of the proposed legislation. Comments and feedback will help the MHRA understand the consequences of the legislation. Please keep your response to under 100 words.

Questions for Healthcare Organisations

This questionnaire is intended for manufacturers, healthcare organisations, Approved Bodies, UK Responsible Persons, and other organisations that may be impacted by The Medical Devices (Amendment) Regulations 2026 (“the 2026 Regulations”). The MHRA aims to gather data on the costs and benefits of the 2026 Regulations that will introduce strengthened pre-market measures for medical devices in Great Britain (England, Scotland, and Wales).

Your participation will help the MHRA understand the impact of the proposed changes. The survey explores the financial implications of all topics covered in The Medical Devices (Amendment) Regulations 2026 allowing you to highlight any economic challenges you face.

Where possible, this questionnaire should be completed by the individual(s) responsible for the relevant question area within the organisation. **Responses should represent the organisation as a whole.**

It is estimated that the questionnaire will take approximately 20 minutes for Healthcare Organisations.

The questionnaire follows three parts:

1. Background and your organisation
2. Questions on the 2026 Regulations
3. Feedback

Background and your organisation

1. Which of the following best describes you or the organisation you work for? If more than one option applies, please select the one that is most relevant. If you wish to reflect multiple roles, please complete separate entries for the survey.
 - a) A manufacturer
 - b) A Healthcare Organisation**
 - c) An Approved Body
 - d) A UK Responsible Person (UKRP)
 - e) A patient or carer
 - f) Other, please specify
2. What best describes your profession?
(Open text box)

Questions on the 2026 Regulations

3. Do you think that the 2026 Regulations will result in increased confidence in the NHS and medical devices?
 - a) Yes
 - b) No

c) Unsure

4. As a result of these regulations being implemented, do you think the proportion of adverse medical device incidents across Great Britain will increase, decrease or stay the same?
- a) Increase
 - b) Decrease
 - c) Stay the same
 - d) I don't know

5. What percentage change in the number of adverse medical device incidents across Great Britain do you expect due to the 2026 Regulations? (e.g. -10% (i.e. reduction) or +10% (i.e. increase). If you are unsure, please enter a range.
(Open text box)

6. Do you believe that the 2026 Regulations will encourage innovation?

*“**Innovation** in healthcare is the process of introducing new ideas, methods, technologies, products, or services aimed at improving healthcare delivery, patient outcomes, and overall efficiency within the healthcare providers (e.g. NHS). It includes the creation and implementation of concepts, ideas, technologies, processes, and services that benefit clinical outcomes and enhance patient experiences.”*

- a) Yes
- b) No
- c) Unsure

7. Please explain your answer to the previous question: ‘do you believe that the 2026 Regulations will encourage innovation?’
(Open text box)

8. Do you think that the 2026 Regulations will result in increased and broader access to innovative devices?

- a) Yes
- b) No
- c) Unsure

9. Have you reported incidents related to medical devices using the MHRA Yellow Card scheme or if you are in Scotland to the Incident Reporting and Investigation Centre (IRIC)?

- a) Yes
- b) No
- c) Unsure

10. Have you ever been part of a recall?

- a) Yes
- b) No
- c) Unsure

The following questions will relate to your estimated additional setup and ongoing annual costs arising from the 2026 Regulations.

11. Assuming conformity assessment costs by conformity assessment bodies (e.g. approved bodies) stay the same, what additional **one-off or setup** costs do you expect your organisation to face once the 2026 Regulations are fully implemented? If unsure, please provide an estimated range (e.g. “£25k-£50k”). Specify the broad categories that are required for one-off or setup costs.

(Open text box)

12. Of these additional one-off or set-up costs, what proportion can be attributed to each of the following areas? Please ensure that percentages total to 100%.

- Definitions used in the legislation
 - Classifications
 - Essential requirements
 - Technical documentation retention periods
 - Equivalence
 - Implant cards
 - Custom-made devices
 - Claims
 - Software as a Medical Device
 - *In vitro* diagnostic (IVDs) devices
 - International reliance
 - Unique Device Identifiers
 - Electronic instructions for use
- (Open text box)

13. If you cannot give a cost estimate breakdown (to the nearest £ '000s) for question 12, please select the areas where you expect to see the highest additional set-up costs.

- Definitions used in the legislation
- Classifications
- Essential requirements
- Technical documentation retention periods
- Equivalence
- Implant cards
- Custom-made devices
- Claims
- Software as a Medical Device
- *In vitro* diagnostic (IVDs) devices
- International reliance
- Unique Device Identifiers
- Electronic instructions for use

14. Assuming conformity assessment costs by conformity assessment bodies (e.g. approved bodies) stay the same, what additional annual or ongoing costs do you expect after implementation of the 2026 Regulations? If unsure, please provide an estimated range (e.g. “£25k-£50k”). Please share a reason for your cost estimate.

(Open text box)

15. Of these additional **ongoing or annual costs**, what proportion can be attributed to each of the following areas? Please ensure that percentages total to 100%.

- Definitions used in the legislation
 - Classifications
 - Essential requirements
 - Technical documentation retention periods
 - Equivalence
 - Implant cards
 - Custom-made devices
 - Claims
 - Software as a Medical Device
 - *In vitro* diagnostic (IVDs) devices
 - International reliance
 - Unique Device Identifiers
 - Electronic instructions for use
- (Open text box)

16. If you can't give a cost breakdown for question 15, please select the areas where you expect to see the highest additional ongoing or annual costs.

- Definitions used in the legislation
- Classifications
- Essential requirements
- Technical documentation retention periods
- Equivalence
- Implant cards
- Custom-made devices
- Claims
- Software as a Medical Device
- *In vitro* diagnostic (IVDs) devices
- International reliance
- Unique Device Identifiers
- Electronic instructions for use

End of questionnaire and feedback

17. Thank you very much for your feedback. Your responses are essential in ensuring the MHRA and the government understand the impacts of these proposed regulatory changes. If you have any other comments you wish to add, please do so below in 100 words or less.

(Open text box)

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.

Guidance on questions for Healthcare Organisations

- **Questions 4 and 5:** These regulations are designed to prevent potential risks and ensure that devices are safe and effective for their intended use. An adverse medical device incident refers to any event that causes, or has the potential to cause, unexpected or unwanted effects involving the safety of device users, including patients or other persons.
- **Question 11:** please provide your best available estimate. An informed estimate is preferable to no response. These costs are in addition to any costs your organisation may have already incurred. Respondents should be aware and take into consideration when providing their costs that there will be appropriate transition periods to ease the compliance burden for businesses. Additional information on the transition arrangements can be found in the 2026 Regulations. One-off or transition costs may include, but are not limited to:
 - Familiarisation and training of staff to understand new requirements
 - Administrative costs for upgrading equipment, IT systems, or facilities to meet new requirements
 - Administrative costs for hiring new staff
- **Questions 12 and 15:** these estimates will be used to inform which parts of the future regulations will have the greatest impact on businesses. Respondents should provide their best available estimate, or range of estimates, ensuring that percentages total to 100%. An informed estimate is preferable to no response. Please see below for an example response:
 - *Definitions used in the legislation – 3%*
 - *Classification – 3%*
 - *Essential requirements – 10%*
 - *Technical documentation retention periods – 5%*
 - *Equivalence – 10%*
 - *Implant cards – 10%*
 - *Custom-made devices – 5%*
 - *Claims – 10%*
 - *Software as a Medical Device – 10%*
 - *in vitro diagnostic (IVDs) devices – 10%*
 - *International reliance – 10%*
 - *Unique Device Identifiers– 10%*
 - *Electronic instructions for use – 4%*
 - It is recognised that there may be overlap between some areas of the new requirements. However, respondents should provide their best estimate of accounting for the combined impact of these two interactions when responding.
 - The relevant pages in the 2026 Regulations for the sections can be found in the [Scope section](#) of the guidance and there is summary table of the proposed changes in [Annex A](#).

- When ranking the areas, consider the following:
 - Familiarisation and Training: Costs associated with training staff to understand and comply with new regulations.
 - Administrative Costs: Costs related to upgrading equipment, IT systems, or facilities to meet new requirements.
 - Staffing Costs: Costs for hiring and maintaining additional staff to manage compliance.
 - Ongoing Training: Costs for continuous training to keep staff updated with regulatory changes.

- **Questions 13 and 16** covers the same points as Questions 12 and 15 but do not require you to add proportions.

- **Question 14:** please provide your best available estimate. An informed estimate is preferable to no response. These costs are in addition to any costs your organisation may have already incurred or set up (for example, from complying with EU MDR/EU IVDR) and are also additional to the familiarisation costs noted in the previous question. Annual ongoing costs may include:
 - Costs of maintaining additional staff
 - Costs of maintaining new equipment or IT systems
 - Costs of maintaining new facilities
 - Costs of ongoing training

- **Question 17:** Please provide any insight on the impact of the proposed legislation. Comments and feedback will help the MHRA understand the consequences of the legislation. Please keep your response to under 100 words.

Questions for Approved Bodies

This questionnaire is intended for manufacturers, healthcare organisations, Approved Bodies, UK Responsible Persons, and other organisations that may be impacted by The Medical Devices (Amendment) Regulations 2026 (“the 2026 Regulations”). The MHRA aims to gather data on the costs and benefits of the 2026 Regulations that will introduce strengthened pre-market measures for medical devices in Great Britain (GB) (England, Scotland, and Wales).

Your participation will help the MHRA understand the impact of the proposed changes. The survey explores the financial implications of all topics covered in The Medical Devices (Amendment) Regulations 2026 allowing you to highlight any economic challenges you face.

Where possible, this questionnaire should be completed by the individual(s) responsible for the relevant question area within the organisation. **Responses should represent the organisation as a whole.**

It is estimated that the questionnaire will take approximately 20 minutes for Approved Bodies.

The questionnaire follows three parts:

1. Background and your organisation
2. Questions on the 2026 Regulations
3. Feedback

Background and your organisation

1. Which of the following best describes you or the organisation you work for? If more than one option applies, please select the one that is most relevant. If you wish to reflect multiple roles, please complete separate entries for the survey.
 - a) A manufacturer
 - b) A Healthcare Organisation
 - c) An Approved Body
 - d) A UK Responsible Person (UKRP)
 - e) A patient or carer
 - f) Other, please specify
2. What is the name of your organisation and approved body number?
(Open text box)
3. What is the most recent year (e.g., 2022) for which you have data on your organisation's turnover from activities within GB?
 - a) April 2024 to March 2025
 - b) April 2023 to March 2024
 - c) April 2022 to March 2023
 - d) April 2021 to March 2022
 - e) April 2020 to March 2021

f) Other
(Open text box)

4. In the most recent year for which you have data, which of the following categories best reflects your organisation's turnover from activities within GB? If you are unsure, you may select up to two categories.
- a) 0 - £49,999
 - b) £50,000 - £99,999
 - b) £100,000 – £499,999
 - c) £500,000 – £999,999
 - d) £1 million – £2.9 million
 - e) £3 million – £5 million
 - g) Other
(Open text box)

Questions on the 2026 Regulations

5. What do you expect the additional one-off/setup costs to your organisation to be once the 2026 Regulations are fully implemented? If you are unsure, you may enter a range (e.g. “£25k - £50k”). Specify the broad categories that are required for additional one-time/setup costs.
(Open text box)
6. What do you expect the annual additional ongoing (excluding setup) costs to your organisation to be once the 2026 Regulations are fully implemented? If you are unsure, you may enter a range (e.g. “£25k - £50k”) Specify the broad categories that are required for annual additional ongoing costs.
(Open text box)
7. Of the additional one-off/setup costs resulting from the measures outlined in the 2026 Regulations, what proportion can be attributed to each of the following areas?
- Definitions used in the legislation
 - Classifications
 - Essential requirements
 - Technical documentation retention periods
 - Equivalence
 - Implant cards
 - Custom-made devices
 - Claims
 - Software as a Medical Device
 - *in vitro* diagnostic (IVDs) devices
 - International reliance
 - Unique Device Identifiers
 - Electronic instructions for use
- (Open text box)

8. If you are unable to provide a proportion in response to the previous question regarding the measures outlined in the Regulations, please select the areas where you expect to see the highest additional one-off/setup costs.
- Definitions used in the legislation
 - Classifications
 - Essential requirements
 - Technical documentation retention periods
 - Equivalence
 - Implant cards
 - Custom-made devices
 - Claims
 - Software as a Medical Device
 - *in vitro* diagnostic (IVDs) devices
 - International reliance
 - Unique Device Identifiers
 - Electronic instructions for use
9. Of the annual additional ongoing (excluding setup) costs resulting from the measures outlined in the 2026 Regulations, what proportion can be attributed to each of the following areas?
- Definitions used in the legislation
 - Classifications
 - Essential requirements
 - Technical documentation retention periods
 - Equivalence
 - Implant cards
 - Custom-made devices
 - Claims
 - Software as a Medical Device
 - *in vitro* diagnostic (IVDs) devices
 - International reliance
 - Unique Device Identifiers
 - Electronic instructions for use
- (Open text box)
10. If you are unable to provide a proportion in response to the previous question, please select the areas where you expect to see the highest additional ongoing (excluding setup) costs. If you are still uncertain, you may skip this question.
- Definitions used in the legislation
 - Classifications
 - Essential requirements
 - Technical documentation retention periods
 - Equivalence
 - Implant cards
 - Custom-made devices
 - Claims
 - Software as a Medical Device

- *in vitro* diagnostic (IVDs) devices
- International reliance
- Unique Device Identifiers
- Electronic instructions for use

11. As a result of these regulations being implemented, do you think the proportion of adverse medical device incidents across Great Britain will increase, decrease or stay the same?

- a) Increase
- b) Decrease
- c) Stay the same
- d) I don't know

12. What percentage change in the proportion of adverse medical device incidents across Great Britain do you expect due to the 2026 Regulations? (e.g. -10% (i.e. reduction) or +10% (i.e. increase). If you are unsure, please enter a range.

(Open text box)

13. Do you believe that the 2026 Regulations will encourage innovation?

“Innovation in healthcare is the process of introducing new ideas, methods, technologies, products, or services aimed at improving healthcare delivery, patient outcomes, and overall efficiency within the healthcare providers (e.g. NHS). It includes the creation and implementation of concepts, ideas, technologies, processes, and services that benefit clinical outcomes and enhance patient experiences.”

- a) Yes
- b) No
- c) Unsure

14. Please explain your answer to the previous question: ‘do you believe that the 2026 Regulations will encourage innovation?’

(Open text box)

End of questionnaire and feedback

15. Thank you very much for your feedback. Your responses are essential in ensuring the MHRA and the government understand the impacts of these proposed regulatory changes. If you have any other comments you wish to add, please do so below in 100 words or less.

(Open text box)

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.

Guidance on questions for Approved Bodies

- **Question 3:** this question has been included because providing the current year allows the turnover data to be adjusted to the current price level, accounting for inflation.
- **Question 4** is designed to determine how representative your organisation is of the wider industry.
 - This data is used to extrapolate the impacts of the legislation to the broader sector, ensuring that all responses are representative. At no point in this questionnaire is any company-specific identifying feature requested, and all responses will be aggregated, so it will not be possible to identify your organisation from the response.
 - Respondents can provide multiple answers to indicate uncertainty. All UK companies are required to file accounts with [Companies House](#), so the turnover of the UK company will usually be retrievable from this website.
 - As always, respondents are only expected to provide their best available answer. Therefore, an informed estimate (or estimates) is preferable to no response.
- **Question 5:** please provide your best available estimate. These costs are in addition to any costs your organisation may have already incurred. Respondents should be aware and take into consideration when providing their costs that there will be a transition period to ease the compliance burden for Approved Bodies. Additional information on the transitional arrangements can be found in the 2026 Regulations. One-off or transition costs may include, but are not limited to:
 - Familiarisation and training of staff to understand new requirements
 - Administrative costs for upgrading equipment, IT systems, or facilities to meet new requirements
 - Administrative costs for hiring new staff
- **Question 6:** please provide your best available estimate. These costs are in addition to any costs your organisation may have already incurred or set up (for example, from complying with EU MDR/EU IVDR) and are also additional to the familiarisation costs noted in the previous question. Annual ongoing costs may include:
 - Costs of maintaining additional staff
 - Costs of maintaining new equipment or IT systems
 - Costs of maintaining new facilities
 - Costs of ongoing training
- **Questions 7 and 9:** these estimates will be used to inform which parts of the 2026 Regulations will have the greatest impact on Approved Bodies. Respondents should provide their best available estimate, or range of estimates, ensuring that percentages total to 100%. Please see below for an example response:
 - *Definitions used in the legislation – 3%*
 - *Classification – 3%*
 - *Essential requirements – 10%*

- *Technical documentation retention periods – 5%*
 - *Equivalence – 10%*
 - *Implant cards – 10%*
 - *Custom-made devices – 5%*
 - *Claims – 10%*
 - *Software as a Medical Device – 10%*
 - *in vitro diagnostic (IVDs) devices – 10%*
 - *International reliance – 10%*
 - *Unique Device Identifiers– 10%*
 - *Electronic instructions for use – 4%”*
- It is recognised that there may be overlap between some areas of requirements. However, respondents should provide their best estimate of accounting for the combined impact of these two interactions when responding.
 - The relevant pages in the 2026 Regulations for the sections can be found in the [Scope section](#) of the guidance and there is summary table of the proposed changes in [Annex A](#).
 - When ranking the areas, consider the following:
 - Familiarisation and Training: Costs associated with training staff to understand and comply with new regulations.
 - Administrative Costs: Costs related to upgrading equipment, IT systems, or facilities to meet new requirements.
 - Staffing Costs: Costs for hiring and maintaining additional staff to manage compliance.
 - Ongoing Training: Costs for continuous training to keep staff updated with regulatory changes.
- **Questions 8 and 10:** cover the same points as Questions 7 and 9 but do not require you to add proportions.
 - **Question 11 and 12:** These regulations are designed to prevent potential risks and ensure that devices are safe and effective for their intended use. An adverse medical device incident refers to any event that causes, or has the potential to cause, unexpected or unwanted effects involving the safety of device users, including patients or other persons
 - **Question 15:** Please provide any insight into on the impact of the proposed legislation. Comments and feedback will help the MHRA understand the consequences of the legislation. Please keep your response to under 100 words.

Questions for UK Responsible Persons

This questionnaire is intended for manufacturers, healthcare organisations, Approved Bodies, UK Responsible Persons, and other organisations that may be impacted by The Medical Devices (Amendment) Regulations 2026 (“the 2026 Regulations”). The MHRA aims to gather data on the costs and benefits of the 2026 Regulations that will introduce strengthened pre-market measures for medical devices in Great Britain (England, Scotland, and Wales).

Your participation will help the MHRA understand the impact of the proposed changes. The survey explores the financial implications of all topics covered in The Medical Devices (Amendment) Regulations 2026 allowing you to highlight any economic challenges you face.

Where possible, this questionnaire should be completed by the individual(s) responsible for the relevant question area within the organisation. **Responses should represent the organisation as a whole.**

It is estimated that the questionnaire will take approximately 20 minutes for UK Responsible Persons (UKRPs).

The questionnaire follows three parts:

1. Background and your organisation
2. Questions on the 2026 Regulations
3. Feedback

Background and your organisation

1. Which of the following best describes you or the organisation you work for? If more than one option applies, please select the one that is most relevant. If you wish to reflect multiple roles, please complete separate entries for the survey.
 - a) A manufacturer
 - b) A Healthcare Organisation
 - c) An Approved Body
 - d) A UK Responsible Person (UKRP)
 - e) A patient or carer
 - f) Other, please specify
(Open text box)
2. Are you based in Great Britain or Northern Ireland?
 - a) Great Britain
 - b) Northern Ireland
3. Do you have a physical address in the UK?
 - a) Yes
 - b) No

4. If you select no to question 3, please explain why you do not have a physical address in the UK.
(Open text box)

Questions on the 2026 Regulations

5. What do you expect the additional one-off/setup costs to your organisation to be once the 2026 Regulations are fully implemented? If you are unsure, you may enter a range (e.g. “£25k - £50k”). Specify the broad categories that are required for additional one-time/setup costs.
(Open text box)
6. What do you expect the annual additional ongoing (excluding setup) costs to your organisation to be once the 2026 Regulations are fully implemented? If you are unsure, you may enter a range (e.g. “£25k - £50k”) Specify the broad categories that are required for annual additional ongoing costs.
(Open text box)
7. Of the additional one-off/setup costs resulting from the measures outlined in the 2026 Regulations, what proportion can be attributed to each of the following areas?
- Definitions used in the legislation
 - Classifications
 - Essential requirements
 - Technical documentation retention periods
 - Equivalence
 - Implant cards
 - Custom-made devices
 - Claims
 - Software as a Medical Device
 - *in vitro* diagnostic (IVDs) devices
 - International reliance
 - Unique Device Identifiers
 - Electronic instructions for use
- (Open text box)
8. If you are unable to provide a proportion in response to the previous question, please select the areas that you think will incur the greatest proportion of additional one-off/setup costs.
- Definitions used in the legislation
 - Classifications
 - Essential requirements
 - Technical documentation retention periods

- Equivalence
- Implant cards
- Custom-made devices
- Claims
- Software as a Medical Device
- *in vitro* diagnostic (IVDs) devices
- International reliance
- Unique Device Identifiers
- Electronic instructions for use

9. Of the annual additional ongoing (excluding setup) costs resulting from the measures outlined in the 2026 Regulations, what proportion can be attributed to each of the following areas?

- Definitions used in the legislation
 - Classifications
 - Essential requirements
 - Technical documentation retention periods
 - Equivalence
 - Implant cards
 - Custom-made devices
 - Claims
 - Software as a Medical Device
 - *in vitro* diagnostic (IVDs) devices
 - International reliance
 - Unique Device Identifiers
 - Electronic instructions for use
- (Open text box)

10. If you are unable to provide a proportion in response to the previous question, please select the areas that you think will incur the greatest proportion of annual additional ongoing (excluding setup) costs.

- Definitions used in the legislation
- Classifications
- Essential requirements
- Technical documentation retention periods
- Equivalence
- Implant cards
- Custom-made devices
- Claims
- Software as a Medical Device
- *in vitro* diagnostic (IVDs) devices
- International reliance
- Unique Device Identifiers
- Electronic instructions for use

11. As a result of these regulations being implemented, do you think the proportion of adverse medical device incidents across Great Britain will increase, decrease or stay the same?
- a) Increase
 - b) Decrease
 - c) Stay the same
 - d) I don't know

12. What percentage change in the proportion of adverse medical device incidents across Great Britain do you expect due to the 2026 Regulations? (e.g. -10% (i.e. reduction) or +10% (i.e. increase). If you are unsure, please enter a range.
(Open text box)

13. Do you believe that the 2026 Regulations will encourage innovation?

*“**Innovation** in healthcare is the process of introducing new ideas, methods, technologies, products, or services aimed at improving healthcare delivery, patient outcomes, and overall efficiency within the healthcare providers (e.g. NHS). It includes the creation and implementation of concepts, ideas, technologies, processes, and services that benefit clinical outcomes and enhance patient experiences.”*

- a) Yes
- b) No
- c) Unsure

14. Please explain your answer to the previous question: ‘do you believe that the 2026 Regulations will encourage innovation?’
(Open text box)

End of questionnaire and feedback

15. Thank you very much for your feedback. Your responses are essential in ensuring the MHRA and the government understand the impacts of these proposed regulatory changes. If you have any other comments you wish to add, please do so below in 100 words or less.
(Open text box)

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.

Guidance on questions for UK Responsible Persons

- **Question 3:** A physical UK address refers to a location that is physically situated within the United Kingdom. This includes a specific place where a person or business can be contacted or where documents can be served. It must be a tangible location such as a house, flat, office, or any other physical structure. The address should not be a virtual office, shell company, forwarding office, or PO Box, as these do not represent a physical presence.
- **Question 5:** please provide your best available estimate. These costs are in addition to any costs your organisation may have already incurred (for example, from complying with EU MDR/EU IVDR). Respondents should be aware and take into consideration when providing their costs that there will be a transition period to ease the compliance burden for Approved Bodies. Additional information on the transition can be found in the [consultation response](#). One-off or transition costs may include, but are not limited to:
 - Familiarisation and training of staff to understand new requirements
 - Administrative costs for upgrading equipment, IT systems, or facilities to meet new requirements
 - Administrative costs for hiring new staff
- **Question 6:** please provide your best available estimate. These costs are in addition to any costs your organisation may have already incurred or set up (for example, from complying with EU MDR/EU IVDR) and are also additional to the familiarisation costs noted in the previous question. Annual ongoing costs may include:
 - Costs of maintaining additional staff
 - Costs of maintaining new equipment or IT systems
 - Costs of maintaining new facilities
 - Costs of ongoing training
- **Question 7 and 9:** these estimates will be used to inform which parts of the future regulations will have the greatest impact on approved bodies. Respondents should provide their best available estimate, or range of estimates, ensuring that percentages total to 100%. Please see below for an example response:
 - *Definitions used in the legislation – 3%*
 - *Classification – 3%*
 - *Essential requirements – 10%*
 - *Technical documentation retention periods – 5%*
 - *Equivalence – 10%*
 - *Implant cards – 10%*
 - *Custom-made devices – 5%*
 - *Claims – 10%*
 - *Software as a Medical Device – 10%*
 - *in vitro diagnostic (IVDs) devices – 10%*
 - *International reliance – 10%*
 - *Unique Device Identifiers– 10%*

- *Electronic instructions for use – 4%”*
- It is recognised that there may be overlap between some areas of requirements. However, respondents should provide their best estimate of accounting for the combined impact of these two interactions when responding.
- The relevant pages in the 2026 Regulations for the sections can be found in the [Scope section](#) of the guidance and there is summary table of the proposed changes in [Annex A](#).
- When ranking the areas, consider the following:
 - Familiarisation and Training: Costs associated with training staff to understand and comply with new regulations.
 - Administrative Costs: Costs related to upgrading equipment, IT systems, or facilities to meet new requirements.
 - Staffing Costs: Costs for hiring and maintaining additional staff to manage compliance.
 - Ongoing Training: Costs for continuous training to keep staff updated with regulatory changes.
- **Question 8 and 10:** covers the same points as Question 7 and 9 but does not require you to add proportions.
- **Question 11 and 12:** These regulations are designed to prevent potential risks and ensure that devices are safe and effective for their intended use. An adverse medical device incident refers to any event that causes, or has the potential to cause, unexpected or unwanted effects involving the safety of device users, including patients or other persons
- **Question 15:** Please provide any insight into on the impact of the proposed legislation. Comments and feedback will help the MHRA understand the consequences of the legislation. Please keep your response to under 100 words.

Questions for patients or carers

This questionnaire is intended for manufacturers, healthcare organisations, Approved Bodies, UK Responsible Persons, patients and other organisations that may be impacted by The Medical Devices (Amendment) Regulations 2026 (“the 2026 Regulations”). The MHRA aims to gather data on the costs and benefits of The Medical Devices (Amendment) Regulations 2026 (“the 2026 Regulations”) that will introduce strengthened pre-market measures for medical devices in Great Britain (England, Scotland, and Wales).

Your participation will help the MHRA understand the impact of the proposed changes. The survey explores the financial implications of all topics covered in the 2026 Regulations allowing you to highlight any economic challenges you face.

Where possible, this questionnaire should be completed by the individual(s) responsible for the relevant question area within the organisation.

It is estimated that the questionnaire will take approximately 15 minutes for patients or carers.

The questionnaire follows three parts:

1. Background questions
2. Questions on the 2026 Regulations
3. Feedback

Background questions

1. Which of the following best describes you or the organisation you work for? If more than one option applies, please select the one that is most relevant. If you wish to reflect multiple roles, please complete separate entries for the survey.
 - a) A manufacturer
 - b) A Healthcare Organisation
 - c) An Approved Body
 - d) A UK Responsible Person (UKRP)
 - e) A patient or carer
 - f) Other, please specify
(Open text box)

Questions on the 2026 Regulations

2. Do you think the 2026 Regulations will improve safety for patients?
 - a) Yes
 - b) No
 - c) Unsure

3. Do you think these proposals could affect some people differently or unfairly? For example, could they have a negative impact on people because of their age, disability, race, sex, or other protected characteristics? Please explain your answer.
(Open text box)

4. Do you believe that the 2026 Regulations will encourage innovation?

“Innovation in healthcare is the process of introducing new ideas, methods, technologies, products, or services aimed at improving healthcare delivery, patient outcomes, and overall efficiency within the healthcare providers (e.g. NHS). It includes the creation and implementation of concepts, ideas, technologies, processes, and services that benefit clinical outcomes and enhance patient experiences.”

- a) Yes
- b) No
- c) Unsure

5. Please explain your answer to the previous question: ‘do you believe that the 2026 Regulations will encourage innovation?’
(Open text box)

6. Do you think that the 2026 Regulations will help more people get access to new and better medical devices

- a) Yes
- b) No
- c) Unsure

7. As a result of these regulations being implemented, do you think the number of adverse medical device incidents across Great Britain will increase, decrease or stay the same?

- a) Increase
- b) Decrease
- c) Stay the same
- d) I don't know

8. What percentage change in the number of adverse medical device incidents across Great Britain do you expect due to the 2026 Regulations? (e.g. -10% (i.e. reduction) or +10% (i.e. increase). If you are unsure, please enter a range.
(Open text box)

9. Do you think that the 2026 Regulations will result in improving patient safety and increased confidence in safety of medical devices in GB?

- a) Yes
- b) No
- c) Unsure

10. Have you reported incidents related to medical devices using the [MHRA Yellow Card scheme](#)?

- a) Yes

- b) No
- c) Unsure

11. Have you ever been part of a medical device safety recall or been aware of any safety issues with any medical devices used in your care?

- a) Yes
- b) No
- c) Unsure

End of questionnaire and feedback

12. Thank you very much for your feedback. Your responses are essential in ensuring the MHRA and the government understand the impacts of these proposed regulatory changes. If you have any other comments you wish to add, please do so below in 100 words or less.

(Open text box)

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.

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Thank you for participating in this survey.

Guidance of questions for patients or carers

- **Questions 7 and 8:** These regulations are designed to prevent potential risks and ensure that devices are safe and effective for their intended use. An adverse medical device incident refers to any event that causes, or has the potential to cause, unexpected or unwanted effects involving the safety of device users, including patients or other persons
- **Question 12:** Please provide any insight into on the impact of the proposed legislation. Comments and feedback will help the MHRA understand the consequences of the legislation. Please keep your response to under 100 words.

Questions for those that selected ‘Other, please specify’

This questionnaire is intended for manufacturers, healthcare organisations, Approved Bodies, UK Responsible Persons, and other organisations that may be impacted by The Medical Devices (Amendment) Regulations 2026 (“the 2026 Regulations”). The MHRA aims to gather data on the costs and benefits of The Medical Devices (Amendment) Regulations 2026 (“the 2026 Regulations”) that will introduce strengthened pre-market measures for medical devices in Great Britain (England, Scotland, and Wales).

Your participation will help the MHRA understand the impact of the proposed changes. The survey explores the financial implications of all topics covered in the 2026 Regulations allowing you to highlight any economic challenges you face.

Where possible, this questionnaire should be completed by the individual(s) responsible for the relevant question area within the organisation. **Responses should represent the organisation as a whole.**

It is estimated that the questionnaire will take approximately 15 minutes.

The questionnaire follows three parts:

1. Background and your organisation
2. Questions on the 2026 Regulations
3. Feedback

Background and your organisation

1. Which of the following best describes you or the organisation you work for? If more than one option applies, please select the one that is most relevant. If you wish to reflect multiple roles, please complete separate entries for the survey.
 - a) A manufacturer
 - b) A Healthcare Organisation
 - c) An Approved Body
 - d) A UK Responsible Person (UKRP)
 - e) A patient or carer
 - f) Other, please specify
(Open text box)

Questions on the 2026 Regulations

2. Do you believe that the 2026 Regulations will encourage innovation?

“Innovation in healthcare is the process of introducing new ideas, methods, technologies, products, or services aimed at improving healthcare delivery, patient outcomes, and overall efficiency within the healthcare providers (e.g. NHS). It includes the creation and implementation of concepts, ideas, technologies, processes, and services that benefit clinical outcomes and enhance patient experiences.”

- a) Yes
 - b) No
 - c) Unsure
3. Please explain your answer to the previous question: '*do you believe that the 2026 Regulations will encourage innovation?*'
(Open text box)
4. Do you think that the 2026 Regulations will result in increased and broader access to innovative devices?
- a) Yes
 - b) No
 - c) Unsure
5. As a result of these regulations being implemented, do you think the proportion of adverse medical device incidents across Great Britain will increase, decrease or stay the same?
- a) Increase
 - b) Decrease
 - c) Stay the same
 - d) I don't know
6. What percentage change in the proportion of adverse medical device incidents across Great Britain do you expect due to the 2026 Regulations? (e.g. -10% (i.e. reduction) or +10% (i.e. increase). If you are unsure, please enter a range.
(Open text box)
7. Do you think that the 2026 Regulations will result in increased confidence in the NHS and medical devices?
- a) Yes
 - b) No
 - c) Unsure
8. Have you reported incidents related to medical devices using the Yellow Card scheme?
- a) Yes
 - b) No
 - c) Unsure
9. Have you ever been part of a recall?
- a) Yes
 - b) No
 - c) Unsure

End of questionnaire and feedback

10. Thank you very much for your feedback. Your responses are essential in ensuring the MHRA and the government understand the impacts of these proposed regulatory changes. If you have any other comments you wish to add, please do so below in 100 words or less.

(Open text box)

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.

Guidance on questions for those that selected ‘Other, please specify’

- **Questions 5 and 6:** These regulations are designed to prevent potential risks and ensure that devices are safe and effective for their intended use. An adverse medical device incident refers to any event that causes, or has the potential to cause, unexpected or unwanted effects involving the safety of device users, including patients or other persons
- **Question 10:** Please provide any insight into on the impact of the proposed legislation. Comments and feedback will help the MHRA understand the consequences of the legislation. Please keep your response to under 100 words.

Frequently Asked Questions for all respondents

- 1) **Question:** I can't answer a question on the questionnaire. Will my questionnaire be discarded?

Answer: No. All responses are useful. If you cannot provide a range of estimates, please state "I don't know"

- 2) **Question:** I've read the 2026 Regulations, but I am still not sure what will be in them. How am I supposed to provide an accurate cost estimate?

Answer: While there is considerable detail in the 2026 Regulations, we recognise the limitations of what information respondents will have to answer the questionnaire. It is likely that there will be additional information in the draft regulatory text when that is published, and the MHRA will be publishing a suite of guidance to support implementation. However, due to the timelines of the impact assessment, it is necessary to circulate this questionnaire prior to the draft regulatory text being published. Please provide your best estimate with the information provided in this guidance document and the linked consultation material.

Annex A

Summary of key provisions in the 2026 Regulations

Topic	Topic summary
Definitions used in the legislation	The SI will revise key definitions to ensure they are appropriate and more closely aligned with international definitions.
Classifications	The SI will update the classification rules for general medical devices, active implantable medical devices, and in vitro diagnostic (IVD) devices, ensuring that the level of scrutiny these devices receive is more commensurate with the risks they present.
Essential requirements	The essential requirements are a list of requirements that manufacturers must meet to ensure the safety and performance of medical devices placed on the GB market. The new regulations will refine and add to the existing essential requirements for medical devices, providing more detailed requirements that keep pace with technological progress developments and align more to international best practices.
Technical documentation retention periods	<p>The SI will mandate certain retention periods for technical documentation to be kept available to the MHRA by UK Responsible Persons and manufacturers.</p> <p>This will enable MHRA to access relevant information in support of compliance activities, facilitate post-market surveillance and vigilance, and facilitate appropriate actions if long-term safety issues occur.</p>
Equivalence	The SI will introduce comprehensive equivalence requirements for general medical devices and active implantable medical devices. This will cover clinical, technical, and biological equivalence, to ensure that these characteristics of the relevant device and the device to which equivalence is claimed are the same, or similar to the extent that there

	<p>would be no clinically significant difference, other than intended improvements, in the safety and clinical performance of the relevant device.</p>
<p>Implant card and patient information</p>	<p>The SI will introduce requirements for manufacturers to provide information about implantable devices, which will be supplied to patients in the form of an implant card and accompanying leaflet.</p> <p>This will ensure patients have accurate information about their implanted device in a standardised format, enabling better informed consent and post-market surveillance.</p>
<p>Custom-made devices</p>	<p>The SI will introduce strengthened requirements for custom-made devices with more comprehensive technical documentation and identifiers to enable the device in question to be identified throughout the supply chain, improving traceability and patient safety. It will enable prescriptions for custom-made devices to be provided electronically. A Class IIb or Class III custom-made implantable device will require a QMS certified by an approved body.</p>
<p>Claims</p>	<p>Claims are information specific to a medical device that ascribe its function, operation and intended use. Claims are often present on packaging, labels, websites, social media platforms, and sales materials.</p> <p>The new regulations introduce requirements to prevent claims that may mislead patients/ users, and will enable MHRA to instruct manufacturers, UKRPs, and others to remove or amend advertising material where claims could mislead and/or adversely affect patient safety.</p>
<p>Devices that are software</p>	<p>The SI will establish cybersecurity requirements for software to align with international best practice. Additionally, it will introduce predetermined change control plans (PCCP) to streamline the regulatory process for software as a general medical device or IVD device, allowing for pre-identification and management of specific change events, thereby reducing administrative burdens for both regulators and manufacturers and ensuring improved product lifecycle management processes.</p>

<p><i>in vitro</i> diagnostic (IVD) devices</p>	<p>Revising the existing IVD classification system to ensure that IVD devices are classified appropriately according to risk to better reflect the public health risks in GB. This will also align GB more closely with the structure used by the IMDRF² and EU to support global harmonisation efforts.</p> <p>Ensuring certain high-risk Class D IVD devices meet stringent safety and performance requirements to protect patient safety where there is high patient risk and harmonising regulatory requirements with Northern Ireland.</p> <p>Eliminating the need for separate validation of COVID-19 tests that have already met the common specifications requirements, thereby streamlining the regulatory process, avoiding duplication, and reducing the burden on businesses.</p>
<p>International reliance</p>	<p>International Reliance aims to improve access to safe quality-assured medical devices for patients in GB, by reducing duplication of regulatory assessments where safe to do so and making use of the expertise and decision-making of other regulatory partners.</p> <p>The MHRA has identified three countries or jurisdictions that have comparable regulatory systems to the UK: Australia, Canada and the USA. The MHRA would rely on the approvals or certificates issued by the regulatory authorities in these comparable regulator countries subject to certain conditions and requirements. For further information please see: Consultation on Medical Devices Regulations: Routes to market and in vitro diagnostic devices - GOV.UK</p>
<p>Unique Device Identifiers</p>	<p>The Unique Device Identifier (UDI) is a series of numeric or alphanumeric characters that is created through internationally accepted device identification and coding standards.</p> <p>Under the new regulations, manufacturers will be required to assign UDIs to medical devices prior to their placement on the GB market. Healthcare professionals and</p>

² [Principles of In Vitro Diagnostic \(IVD\) Medical Devices Classification \(imdrf.org\)](#)

	<p>organisations will also need to ensure that the UDI for implantable medical devices is recorded and linked to the patient in whom the device has been implanted.</p> <p>Mandates manufacturers to assign the UDI to devices before placing them on the market to support traceability, transparency and patient safety.</p>
Electronic instructions for use	<p>The Pre-market SI will extend eIFU to software intended for non-professional end users, provided that certain requirements are met e.g., risk assessments</p>

Annex B

Summary of international reliance routes

Route	Eligible Devices	Approved Body Review
Route 1	<p>Low risk devices that comply with devices legislation in Australia, Canada and the USA:</p> <ul style="list-style-type: none"> - Class I medical devices (MDs), other than software or Class Is/m (Is: Class I sterile device; Im: Class I device with a measuring function) - Non-sterile Class A IVD devices 	<p>No approved body review is required.</p> <p>A self-declaration for an appropriate Quality Management System (QMS) must be provided to the MHRA during registration</p>
Route 2	<p>Devices that comply with device legislation in Australia, Canada (using Class III or Class IV licence) and the USA (using De Novo, PMA or 510(k))*:</p> <ul style="list-style-type: none"> - Class Is/m, IIa, IIb, III** MDs - Sterile Class A IVD devices - Class B, C IVD devices <p><i>*Excluding devices listed in Route 4</i></p> <p><i>**For devices from Canada, only devices with a Class IV licence in Canada would be able to enter this route as a Class III device in GB</i></p>	<ul style="list-style-type: none"> (a) Confirm CRC marketing authorisation (b) Confirm device's GB classification (c) Confirm GB requirements (d) Review PMS plan (e) Review PMS data from last 5 years where available (f) Confirm that the implant card and patient leaflet, if applicable, meets the (updated) UK MDR requirements (g) Confirm that the instructions for use provided with reusable devices, if applicable, contains information on the appropriate processes to allow reuse, including cleaning, disinfection, packaging and, where appropriate, the method of sterilisation, and any restriction on the number of reuses
Route 3	<ul style="list-style-type: none"> - Class IIa, IIb and III MDs that comply with 510(k) legislation in the USA - medical devices that incorporate an ancillary medicinal substance from Australia, Canada or the USA - Class D IVD devices that comply with devices legislation in Australia, Canada and the USA 	<ul style="list-style-type: none"> (a) Perform (a) – (g) in Route 3, and (b) Confirm that the rationale for equivalence to a predicate device for 510(k) devices meets the (updated) UK MDR requirements (c) Obtain an opinion on the quality and safety of any medicinal substance incorporated into the device from the Secretary of State

	<p>-Class Im, IIa, IIb and III MDs that are software that comply with device legislation in Australia, Canada (using Class III or Class IV license) and the USA (using De Novo, PMA or 510(k))*:</p> <p><i>* For devices from Canada, only devices with a Class IV licence in Canada would be able to enter this route as a Class III device in GB</i></p>	<p>(d) Confirm Class D IVD devices meet batch verification requirements</p> <p>(e) For software as a medical device, review information that demonstrates there are no differences between the CRC and GB that adversely impact on the safety or efficacy of the device and the appropriateness of any pre-determined change control plans.</p>
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The following devices would not be eligible for any of the access routes:

- devices granted market access in CRC via reliance routes.
- devices that contain non-viable cells and tissues of human origin.
- devices that are manufactured utilising animal tissue or derivatives, other than an IVD device.
- co-packaged with a medicinal product
- companion diagnostic devices

Annex C

Mapping current classes to future IMDRF classes

From current IVD classification	To new IVD Classification	Examples
List A (ABO blood grouping, Rhesus system, anti-Kell)	D	Hepatitis B/C/D, HIV 1&2, HTLV I & II, ABO blood grouping system, Rhesus system, Anti-Kell
List B (anti-Duffy, anti-Kidd, anti-erythrocytic antibodies, rubella, taxoplasmosis, phenylketonuria, cytomegalovirus, chlamydia, HLA tissue typing, PSA, trisomy 21, measurement of blood sugars)	D	Anti-Duffy, Anti-Kidd
	C	Determine foeto-maternal blood group incompatibility (Trisomy 21), or HLA tissue typing (DR/A/B), Cytomegalovirus, PSA & cancer tests, Chlamydia trachomatis, rubella, taxoplasmosis, Blood sugar measurement
	B	Anti-erythrocytic antibodies
Self-test	C	All self-tests where it does determine a critical situation*
	B	Self-tests for non-critical situations eg. Fertility tests
General	D	Variant Creutzfeldt-Jakob disease, Epstein-Barr virus infection, Treponema pallidum, Trypanosoma cruzi, COVID-19 tests
	C	Tests for transfusion/transplantation or cell administration, Genetic/Genomic tests, companion diagnostics, congenital disorders in foetus, Neisseria gonorrhoeae, Neisseria meningitidis or Cryptococcus neoformans, Chlamydia pneumoniae, G6PD, Troponin
	B	Blood gases, H. pylori test, liver function test for AST/ALP, Urinalysis controls and chemistry controls and controls without a quantitative or qualitative assigned value
	A	Specimen receptacle, culture media, wash solutions, instruments and analysers

*critical situation is a situation or condition where accurate and/or timely diagnosis or treatment action is vital to avoid death, long-term disability or other serious deterioration of health of an individual patient or to mitigating impact to public health.

Proposed IVD routes to market for each class for the UK

Classification System	Risk level	Market Access	Specific Requirements
Class A*	Low Individual Risk and Low Public Health Risk	UKCA self-declaration of conformity	<ul style="list-style-type: none"> • Self-declaration against the relevant Essential Requirements • Ensure the device fulfils the applicable obligations described in IVDD Annex III
Class B* (incl. self-test devices not in a critical situation)	Moderate Individual Risk and/or Low Public health Risk	UKCA self-declaration of conformity + QMS certification	<ul style="list-style-type: none"> • Self-declaration against the relevant Essential Requirements • Ensure the device fulfils the applicable obligations described in IVDD Annex III • QMS certification to ISO13485, issued by a certification body accredited by UKAS
Class C (incl. self-test)	High Individual Risk and/or Moderate Public Health Risk	UKCA conformity assessment by an Approved Body	<ul style="list-style-type: none"> • IVDD Annex IV Audit of QMS or MDSAP • Audit technical documentation (sample only)
Class D	High Individual Risk and High Public Health Risk	UKCA conformity assessment by an Approved Body	<ul style="list-style-type: none"> • Design dossier review • IVDD Annex IV Audit of QMS or MDSAP • Batch released by approved body • Common Specification requirements

**If a Class A or B IVD device is required to be sterile then it will need to undergo a conformity assessment by an approved body only for sterility*