



Medicines & Healthcare products
Regulatory Agency

Government response to the consultation on Medical Devices Regulations: Routes to market and in vitro diagnostic devices

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Ministerial Foreword

This government was elected with a clear mandate: to fix our broken NHS, drive economic growth and usher in a decade of national renewal. Central to all three will be harnessing the UK's world-class Life Sciences and MedTech sectors to deliver transformational improvements in patient care. Unlocking this enormous potential will need a regulatory environment fit for the future – one that protects patient safety, fosters innovation, and accelerates access to cutting-edge MedTech. A leading regulatory environment will support the three big shifts we must realise in our NHS: bringing our analogue NHS into the digital age; moving care from hospital to care in our communities; and focusing on prevention over treatment. The [Medical Devices Regulations: Routes to Market and In Vitro Diagnostic Devices](#) consultation was an important step towards this.

The consultation proposed changes to the regulatory framework on international reliance, the UKCA marking and Class B in vitro diagnostic devices. These are vital proposals to get right to ensure patient safety and equip the NHS with cutting edge MedTech. However, these are a part of a broader set of legislative reforms designed to keep our regulators up to date with the rapid pace of advancements in technology and modernise medical device regulation in Great Britain.

These reforms will also contribute to this government's central growth agenda. Innovators must not be held back by a complex and unpredictable regulatory system. MedTech is a hidden gem of the UK economy, and there is a powerful strategic opportunity to unlock this sector, in which the MHRA has a central role to play.

I would like to say a heartfelt thank you to all who have taken time to engage thoughtfully with this consultation and the MHRA's regulatory reform programme. Your responses are a rallying call for the government to deliver change, and the insights you share are helping to shape a system that enhances patient safety, supports innovation, and delivers an NHS fit for the future.

Baroness Merron

**Parliamentary Under-Secretary of State for Patient Safety,
Women's Health and Mental Health**

Executive Summary

This document sets out the responses to the public consultation [Medical Devices Regulations: Routes to market and in vitro diagnostic devices](#). The consultation ran from 14 November 2024 to 5 January 2025 and received 287 responses in total from various stakeholders, such as medical device manufacturers and suppliers, healthcare professionals, trade associations, and individuals.

The consultation sought views on proposals in four key areas. One of those proposals was more time-critical than the others and so the government's approach to four pieces of assimilated EU law was [published](#) on 26 February 2025 and the resulting legislation came into force on 24 May 2025.

This document sets out our response to the consultation proposals relating to international reliance, UKCA marking and the regulation of Class B *in vitro* diagnostic devices. These are all vital considerations for a regulatory framework that increases patient safety and the availability of devices on the market. Nevertheless, they are just a small part of the broader set of legislative reforms that will ensure our regulation of medical devices is up to date and able to address advances in technology.

The government has considered its approach to each of these proposals in light of the responses received, and can be summarised as follows:

1. International reliance

The consultation set out a number of proposals about the detail of a future international reliance scheme, which would enable swifter market access for certain devices that have already been approved in a comparable regulator country. The government intends to implement three of the proposed routes to market and expand the scope of the scheme to include software as a medical device and implantable Class IIb and Class III medical devices that comply with 510(k) legislation in the USA, subject to the demonstration of entire equivalence. Detailed guidance will be published to support this scheme. The approach for CE marked medical devices will undergo further consultation.

2. UKCA marking

The consultation sought views on removing the requirement for UKCA marking for devices and their associated labelling (e.g. packaging and instructions for use) which have undergone the UKCA process. Once the separate requirement is in place for Unique Device Identification, the government intends to remove the requirement for UKCA marking.

3. *In vitro* diagnostic (IVD) devices

The consultation proposed a more risk proportionate approach to the regulatory requirements for market access for IVD devices. The government will amend the conformity assessment routes for Class B IVD devices (including software IVD devices), requiring UKCA self-assessment of conformity with the regulations and Quality Management System (QMS) certification to ISO 13485 before they can be placed on the Great Britain market. QMS certification issued by UKAS accredited bodies or, for Comprehensive and Progressive Agreement for Trans-Pacific Partnership (CPTPP) countries, International Accreditation Forum (IAF) accredited bodies will be permitted. To ensure that manufacturers are able to comply with the updated requirements, the transition period will be commensurate with the scale of the changes and comprehensive guidance will be published. Class A and B IVD devices will remain in scope of the international reliance scheme.

The proposed approaches above apply to the medical device regulatory framework for Great Britain. For guidance on the regulation of devices in Northern Ireland, see [Regulation of devices in Northern Ireland](#).

Introduction

The Medicines and Healthcare products Regulatory Agency (MHRA) is the UK government agency responsible for the regulation of medical devices.

Medical devices are products or equipment that are used for medical purposes, such as diagnosis, prevention, monitoring or treatment of diseases or injuries. They include a wide range of products, such as pacemakers, artificial hips, blood glucose meters, pregnancy tests, medical decision support software, syringes, surgical instruments and wheelchairs.

The MHRA puts patients first in everything we do, right across the lifecycle of the products we regulate, and we ensure that medicines and healthcare products available in the UK are effective and acceptably safe. The MHRA wants to develop a future regime for medical devices that enables:

- strengthened patient and public safety;
- innovation;
- close alignment with international best practice;
- earliest possible access to medical devices; and
- risk proportionate regulation of medical devices.

As set out in the consultation document, the MHRA intends to update the regulatory framework to improve the scrutiny and oversight of medical devices. This 'Pre-Market' legislation will ensure that appropriate measures are in place before a device can be put on the market. Amongst other things, this will include measures for unique device identifiers, implant cards, new rules to ensure that claims are consistent with intended purpose and changes to the classification of some medical devices such as implantables and IVD devices.

The legislation will have a significant impact on patient safety, while the new international reliance scheme will improve patients' ability to safely access the devices they need. The draft legislation will be published on the World Trade Organization website in the coming weeks.

The legislation will be informed by the results of this public consultation, as well as previous public consultations.

Respondents

This consultation received 287 responses, from those either responding on behalf of an organisation or as an individual sharing professional or personal views. Table 1 below shows the breakdown of respondents.

Table 1. Type of respondent

Type of individual	Number of responses	Percentage of total responses
Organisation	180	63%
Individual sharing professional views	88	31%
Individual sharing personal views	19	7%

The organisations that responded to the consultation represented a variety of sectors and interests, such as device manufacturers, healthcare professionals, trade associations, academic institutions, and patient groups; most responses were submitted by businesses. Table 2 below shows the breakdown of the type of organisations that responded to the consultation, although it should be noted that not all respondents provided this demographic information.

Table 2. Type of organisation and number of responses

Types of organisation	Number of responses	Percentage of responses provided
Business	162	56%
Trade association	20	7%
Professional regulator	15	5%
Research organisation	9	3%
Professional representative group	10	3%
NHS	2	1%

Patient group	2	1%
All other responses	48	17%
No response	19	7%

Those who responded as an organisation or as an individual sharing their professional views were asked where their organisation operates. The majority of those respondents operate in England, followed by locations outside of the UK, Wales, Scotland and Northern Ireland. It should be noted that the proposal only applies to Great Britain. Table 3 below shows the breakdown of these locations; respondents were able to select more than one location, or none at all.

Table 3. Location of organisation

Location of organisation	Number of responses	Percentage of responses provided
England	212	80%
Outside the UK	160	60%
Wales	120	45%
Scotland	115	43%
Northern Ireland	106	40%

The majority of the individuals sharing personal views were also based in England, followed by Wales, locations outside the UK, and Scotland. Table 4 below shows the breakdown of the locations of the respondents.

Table 4. Location of individuals

Location of individuals	Number of responses	Percentage of responses provided
England	14	74%
Wales	2	11%
Outside the UK	2	11%
Scotland	1	5%

International Reliance

Background

The MHRA has identified four countries or jurisdictions that have comparable regulatory systems to Great Britain (GB), namely Australia, Canada, the EU and the USA. The MHRA is proposing to rely on the approvals or certificates issued by the regulatory authorities in these comparable regulator countries (CRCs), subject to certain conditions and requirements.

The aim of this framework is 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. It would also enable regulatory resource, and manufacturer resource, to be focused on more [innovative products](#) for the benefit of patient health.

Proposal

The [proposed framework](#) has four access routes for different device classes and types. Certain devices would be eligible to undergo a streamlined review process compared to the UKCA conformity assessment, due to reliance on assessments that have already been performed in Australia, Canada, the EU or the USA.

Devices would need to be registered with the MHRA and meet GB-specific requirements. These requirements include having English language labelling and packaging, a UK Responsible Person, a unique device identifier (UDI), and complying with post-market surveillance (PMS) requirements.

Feedback

The consultation invited views on whether respondents agreed with all elements of the MHRA's four proposed international reliance routes.

Of the 287 responses received:

- 143 (50%) supported the proposal without further comments on the proposed routes
- 130 (45%) went on to comment on each proposed route separately, and the feedback is summarised in the following paragraphs
- 14 (5%) had no opinion

Route 1

The consultation invited views on whether respondents would like to see the proposed Route 1 introduced.

Of the 287 responses received:

- 234 (82%) supported the proposal
- 29 (10%) did not support the proposal
- 24 (8%) had no opinion

Comments from those who supported this proposal agreed with the aim to align with international best practice and facilitate timely patient access to medical devices. Questions were raised about what methods would be in place to ensure Route 1 devices comply with PMS regulations after initial acceptance, applicability for Class I reusable (Ir) devices with EU Medical Devices Regulation (EU MDR) approval, and there were requests for guidance regarding what will be considered an appropriate quality management system.

Comments from those who did not support this proposal included concerns about whether manufacturers would use this route in cases where devices were deemed Class I in the CRC but would be classified as Class IIa or higher in GB. Some suggested this was an unnecessary route for devices since manufacturers can already self-declare to the UKCA requirements for Class I medical devices and Class A IVD devices. Some thought the self-declaration for this route should include all essential requirements in the Medical Devices Regulations 2002 (MDR 2002) to ensure consistency.

There were also requests for the scope of Route 1 to be expanded further to include all CE marked devices, regardless of class.

Route 2

The consultation invited views on whether respondents would like to see the proposed Route 2 introduced.

Of the 287 responses received:

- 218 (76%) supported the proposal
- 48 (17%) did not support the proposal
- 21 (7%) had no opinion

Comments from those who supported this proposal generally noted that reliance was seen as a positive development. Respondents requested further clarification on the GB requirements expected to be met. There were also calls for transparency regarding

costs and timelines associated with this route, as well as the inclusion of active CE marked devices in this route. Additionally, questions were raised about the process when the GB classification of a device differs from the EU classification, and whether EU MDR 'Annex XVI devices' (i.e. products with a similar risk profile to medical devices without an intended medical purpose) would be included in this route.

Comments from those who did not support the proposal expressed concerns that the approved body pre-market review might be repetitious and lead to unnecessary costs and delays compared to the current transitional arrangements for CE marked medical devices. The transitional arrangements allow CE marked devices from the EU to be placed on the GB market [until 30 June 2028 or 30 June 2030, depending on the device, to support the transition to our updated regulatory framework following EU exit.](#)

Comments common to both groups of responders (yes and no) suggested continued recognition of CE marked devices beyond 2030. Alternatively, some respondents requested that the MHRA conduct the pre-market review internally.

Route 3

The consultation invited views on whether respondents would like to see the proposed Route 3 introduced.

Of the 287 responses received:

- 204 (71%) supported the proposal
- 48 (17%) did not support the proposal
- 35 (12%) had no opinion

Comments from those who supported this proposal were similar to those received for Route 2 and generally noted that reliance was seen as a positive development. Further clarification was requested on the GB requirements expected to be met. There were also calls for transparency regarding costs and timelines associated with this route. Additionally, requests were made for medical devices that utilise animal tissues, medicinal products that include a medical device in the secondary packaging of the medicinal product and companion diagnostics to be included in this route. Guidance regarding what will be considered an appropriate quality management system for this route was also requested.

Comments from those who did not support this proposal expressed concerns that this scheme was not supportive of the UK life sciences industry and a preference to only have international reliance for CE marked devices. Some respondents suggested that, while they were broadly supportive of international reliance, they thought the proposed level of approved body review was too high with unnecessary documentary burdens.

Others thought that the proposed level of approved body review was too light and suggested that this route should include a review of clinical data.

Route 4

The consultation invited views on whether respondents would like to see the proposed Route 4 introduced.

Of the 287 responses received:

- 200 (70%) supported the proposal
- 58 (20%) did not support the proposal
- 29 (10%) had no opinion

Comments from those who supported this proposal were similar to those received for Routes 2 and 3. Additionally, there were requests to expand the scope of this route to include software as a medical device and implantable devices approved via 510(k). Some believed demonstrating 'entire equivalence' according to Annex C in the consultation might be challenging, while others thought this review step would be repetitious and suggested its removal to expedite access to these devices. There were also suggestions for CE marked active devices and their associated requirements to be moved into Route 2 for efficiency. Guidance on batch release testing for Class D IVD devices and requirements for software as a medical device and significant changes were requested. Additionally, there were calls to consider a risk-based approach for software as a medical device.

Comments from those who did not support this proposal expressed concerns that this initiative was not supportive of the UK life sciences industry, and that separating active devices into this route was not necessary. There were some requests to clarify whether the 'entire equivalence' requirements were applicable for IVD devices. As with Route 3, some respondents suggested that, while they were broadly supportive of reliance, they thought the proposed level of approved body review, especially for equivalence and ancillary medicinal substances, was too high with unnecessary documentary burdens. Others thought that the proposed level of approved body review was too light and requested further technical review against the MDR 2002 essential requirements.

Scope of Route 4

The consultation invited views on whether respondents would like to add software as a medical device and all implantable Class IIb and Class III devices approved via 510(k) into the scope of the proposed Route 4 if their rationale for equivalence meets the new MDR 2002 requirements for entire equivalence on a biological, technical and clinical basis.

Of the 287 responses received:

- 169 (59%) supported the proposal
- 54 (19%) did not support the proposal
- 64 (22%) had no opinion

Comments from those who supported this proposal conveyed general agreement with the suggested approach. Some believed demonstrating 'entire equivalence' according to Annex C in the consultation would be challenging, which may limit the usability of this route, while others thought this review step was duplicative and suggested its removal to expedite access to these devices.

Comments from those who did not support this proposal thought that the equivalence requirements were too stringent. Other respondents thought that additional scrutiny was required, particularly for software as a medical device that incorporates artificial intelligence and suggested more focus on clinical data for implantable devices. There were also calls to consider a risk-based approach for software as a medical device.

Government response

The broadly positive response to the proposed international reliance framework is indicative of the support to facilitate timely patient access to safe and effective medical devices.

Having considered the views of all respondents, taking into account concerns and suggestions, the government intends to proceed with implementing the proposed international reliance Routes 1, 3 and 4 for medical devices. Additionally, the proposed scope of Route 4 will be expanded to include software as a medical device and implantable Class IIb and Class III medical devices that comply with 510(k) legislation in the USA, subject to the demonstration of entire equivalence.

We recognise that a recurring theme in the consultation responses was the request to indefinitely extend the recognition of CE marked medical devices in accordance with current transitional arrangements, to deliver uninterrupted market access to devices for patients. Therefore, we intend to consult further on the international reliance routes for CE marked devices and will not implement the proposed routes for CE marked devices in Routes 1, 2, and 4 at this time. We will consult further in due course on our approach for these devices.

We also acknowledge and accept the request to restructure the proposed access routes so that active devices are not separated into Route 4 to enhance operational efficiency

for these devices. The eligibility for each route will be based on classification and type of prior approval.

To support the introduction of these reliance routes, guidance will be created that addresses specific questions raised during the consultation, such as the requirements that will apply to software and Class D in vitro diagnostic devices.

Additionally, we would like to clarify that:

- Devices without an intended medical purpose are not currently in the scope of the MDR 2002 and therefore would not be eligible for international reliance.
- Devices must be classified in accordance with the MDR 2002. In the event of a dispute between a manufacturer and an approved body over the classification of a device, the matter shall be referred to the Secretary of State, who shall determine the classification of the device in accordance with the relevant classification criteria.

We have also received questions about why the proposed approach would have only allowed companion diagnostics through Route 2 (i.e. with CE marking in accordance with the EU IVD Regulations (EU IVDR)). A companion diagnostic means a device which identifies, whether before or during treatment:

- (a) patients who are not likely to benefit from a medicinal product, or
- (b) patients who are likely to be at increased risk of serious adverse reaction as a result of treatment with a medicinal product.

Medicinal products are granted a UK-wide marketing authorisation, meaning that any associated device must be approved for use in both GB and Northern Ireland (NI). The EU IVDR applies in NI, hence CE marked devices would have been eligible for the proposed scheme. As detailed above, we will consult further in due course on our approach to CE marked devices.

UKCA marking

Background

Currently, medical devices, or their sterile pack, need to have a UKCA marking to be placed on the GB market if they have undergone the UK conformity assessment process, where practical and appropriate.

The consultation proposed to remove the requirement for a UKCA marking due to the intention to require manufacturers to assign Unique Device Identification (UDI) to medical devices before they are placed on the GB market. This aims to improve the traceability of medical devices.

A UDI is a series of numeric or alphanumeric characters that is created through a globally accepted device identification and coding standard. It looks like a barcode and allows the unambiguous identification of a specific medical device on the market. The UDI is unique to the medical device itself, enabling us to identify the medical device and who manufactured it or placed it on the market. In the future, it would also be searchable in a public-facing database, where the device's conformity assessment process could be verified.

Proposal

The MHRA proposed to remove the requirement for UKCA marking for devices which have been through the UK conformity assessment process. This would mean that a UKCA marking would not be required on the device or its labelling (e.g. packaging and instructions for use).

The conformity assessment process would not be impacted by this proposal. Marking requirements from other product safety or health and safety legislation, such as electrical equipment safety and restriction of the use of certain hazardous substances (RoHS) in electrical and electronic equipment, would still apply to certain devices, where applicable. It would be the responsibility of the manufacturer to ensure they meet the appropriate requirements for other applicable legislation.

Feedback

The consultation invited views on whether respondents supported the proposal to remove the UKCA marking requirement for devices which have been through the UK conformity assessment process.

Of the 287 responses received:

- 204 (71%) supported the proposal
- 66 (23%) did not support the proposal
- 17 (6%) had no opinion

Comments from those who supported this proposal suggested that it would reduce regulatory burden and cost, and improve time-to-market, especially for small and medium-sized enterprises. There was general agreement that adding a UKCA marking directly to a device may be a barrier to trade and market access. Respondents agreed that MHRA registration and UDI could be used to verify information regarding conformity assessment in the future. Some respondents highlighted that their support was conditional on UDIs being implemented and publicly accessible, as well as the provision of education for healthcare professionals and the public. Additionally, some respondents suggested that medical devices with a UKCA marking already in the supply chain should be allowed to remain in distribution, suggesting that there should be a transition for removal of requirements for UKCA marking or acceptance of a mark until their next labelling change.

Comments from those who did not support this proposal thought having a UKCA marking was a useful quick visual indicator for whether a device has undergone conformity assessment, and for importers and distributors to verify conformity. Additionally, concerns were raised that removing this requirement could result in re-labelling activities and additional efforts for manufacturers who have already implemented the UKCA marking on their devices. Some feedback also highlighted the usefulness of the UKCA marking for software as a medical device, noting that it does not create a trade barrier for these devices. Others thought this proposal was only acceptable for dual marked UKCA/CE devices which already display a CE marking on the device.

The consultation also invited views on whether respondents supported the proposal to remove the UKCA marking requirement for medical device labelling (e.g. packaging and instructions for use) for devices which have been through the UK conformity assessment process.

Of the 287 responses received:

- 189 (66%) supported the proposal
- 83 (29%) did not support the proposal
- 15 (5%) had no opinion

Comments from those who supported this proposal were consistent with those received for the previous question. Respondents suggested this would reduce regulatory burden and cost, and improve time-to-market, especially for small and medium-sized enterprises. There was general agreement that adding a UKCA marking to a device's labelling may be a barrier to trade and market access. Some respondents highlighted that their support was conditional on UDIs being implemented and publicly accessible, as well as the provision of education for healthcare professionals and the public. Additionally, some respondents encouraged the MHRA to go further by expanding digital labelling solutions to further improve market access, such as expansion of electronic instructions for use and allowing the UKRP address to be provided digitally.

Comments from those who did not support this proposal included suggestions that it could create confusion for healthcare professionals who check device labelling before use. Others thought this was acceptable for healthcare systems who have scanning technology in place, but not for lay users unfamiliar with UDI. Some respondents agreed with removing the requirement for a UKCA marking but felt that retaining the UKCA marking on the labelling is important to avoid digital exclusion. Additionally, there were concerns that removing this requirement could result in re-labelling activities and additional efforts for manufacturers who have already implemented the UKCA marking on their labelling. Others thought this proposal was only acceptable for dual marked UKCA/CE devices which already display a CE marking on their labelling.

Government response

The MHRA has carefully considered all the responses to both questions proposed in this section of the consultation and recognise the largely supportive nature of the feedback. Most respondents expressed support for removing the requirement for UKCA marking for devices and their associated labelling.

The government intends to proceed with removing the requirement for UKCA marking for devices, and their associated labelling, that have been through the UK conformity assessment process.

The removal of this requirement will be conditional on:

- manufacturers assigning UDI to the device, and
- the UDI being searchable in a public-facing database.

This policy change will therefore only be implemented after the updated database is operational and the transitional period for the introduction of UDI has concluded. We will

keep stakeholders informed about expected timelines for the implementation of this change.

We would like to address the concerns that removing this requirement could result in re-labelling activities. Although the requirement for mandatory UKCA marking is intended to be removed, it would then become optional for manufacturers to apply a UKCA marking where the device conforms to the relevant requirements in the MDR 2002. This means that there would be no requirement to remove the UKCA marking from devices, and their associated labelling, where this is already present.

***In Vitro* Diagnostic Devices**

Background

In vitro diagnostic (IVD) devices play a crucial role in healthcare by enabling the detection, diagnosis, and management of various medical conditions. These devices range from simple tests, such as pregnancy tests, to complex laboratory equipment used for genetic testing. Given their importance, it is essential that IVD devices meet high standards of safety, quality, and performance to protect public health.

Under the current MDR 2002, IVD devices are classified using a list-based classification system based on their impact on patient and public health. However, the existing classification system is outdated, reflecting past high-risk diseases rather than current health challenges.

In September 2021, the MHRA initiated a consultation that proposed amending the IVD device classification system to align with the principles developed by the International Medical Device Regulators Forum (IMDRF). The proposed changes revise the IVD device classification system to more accurately represent the risk levels associated with current and future health challenges.

The proposed new system will shift from the existing list-based classification to a risk-based framework, aligning more closely with the IMDRF principles. This approach will introduce four classes: A, B, C, and D, with Class A being the lowest risk and Class D being the highest. This classification system will determine the regulatory requirements, which become more stringent with higher risk levels. The aim is to ensure patient safety while avoiding unnecessary regulatory burdens for low-risk IVD devices.

Proposal

The consultation launched in November 2024 proposed to amend the conformity routes to market for Class B IVD devices. Under the proposed classification system, Class B devices would require both a UKCA self-declaration of conformity and Quality Management System (QMS) certification to ISO 13485 issued by a UK Accreditation Service (UKAS) accredited body. This change was proposed to ensure that the market access requirements for low-medium risk IVD devices are more risk proportionate.

The proposed conformity assessment procedures for each risk class were as follows:

- Class A IVD devices: UKCA self-declaration of conformity.
- Class B IVD devices: UKCA self-declaration of conformity + QMS certification.

- Sterile Class A and B IVD devices: Class A or Class B route + UKCA conformity assessment by an approved body for sterility requirements only.
- Class C IVD devices: UKCA conformity assessment by an approved body.
- Class D IVD devices: UKCA conformity assessment by an approved body + batch release testing + common specification requirements.

The proposal also noted the government's intention to update the essential requirements for IVD devices to align more closely with EU IVDR and ensure that IVD devices placed on the market would be of high quality and safe for use, as set out in the [response to the 2021 consultation](#). However, each conformity assessment procedure would need to align with the requirements and obligations in the EU IVD Directive (EU IVDD) Annex III, IV, V, VI or VII, depending on the classification.

Feedback

Of the 287 respondents to the proposal to amend the conformity assessment routes for IVD devices (including software IVD devices) in GB:

- 138 (48%) supported the proposal
- 19 (7%) did not support the proposal
- 130 (45%) had no opinion

Comments from those who supported this proposal generally agreed with the conformity assessment routes for IVD devices. They recommended adopting a risk-based regulatory approach, tailoring the level of scrutiny to the device's risk level and ensuring that high-risk devices receive more stringent controls. There was widespread support for accepting QMS certification issued by non-UKAS accredited bodies, as internationally recognised standards are believed to enhance the quality and safety of medical devices. Improved regulatory frameworks aligning closely with EU regulations were seen as beneficial for reducing inconsistencies and facilitating market access. This alignment helps manufacturers streamline processes and reduce the complexity of complying with different regulatory requirements across regions.

Comments from those who did not support this proposal expressed concern about misalignment with EU regulations, particularly for Class B self-tests and conformity assessment routes. They argued that such misalignment could create market access barriers and increase the regulatory burden on manufacturers. Concerns were also raised about the need for UK-specific accreditation and differing conformity assessment routes for NI and GB, which could lead to confusion and additional regulatory hurdles. Additional costs associated with QMS certification for self-test devices and UKAS

accreditation were highlighted as potential financial burdens. Respondents emphasised the need for detailed guidelines and procedures to manage the unique risks associated with software used in IVD devices and requested a reasonable transition period to allow manufacturers to adapt to the new regulations.

Pre-market requirements

Of the 287 respondents to the proposal to require UKCA declaration of conformity and QMS certification as adequate pre-market requirements for Class B IVD devices:

- 110 (38%) supported the proposal
- 40 (14%) did not support the proposal
- 137 (48%) had no opinion

Comments from those who supported this proposal generally believed that Class B devices, although not as high-risk as Class C or D devices, still require stringent controls to ensure their safety and effectiveness, with QMS certification being sufficient.

Comments from those who did not support this proposal raised concerns about the adequacy of pre-market controls for Class B devices. They noted that manufacturers might down-classify medium-risk products to avoid stringent controls, potentially compromising patient safety. There were calls for more controls and higher scrutiny for Class B self-test devices due to the risk of patient misinterpretation. These devices are used directly by patients without professional supervision, increasing the risk of incorrect usage and interpretation.

Suggestions were made to include other internationally recognised certification bodies, rather than limiting certification to UKAS alone, to provide more flexibility and options for manufacturers. Additionally, the recognition of the Medical Device Single Audit Program (MDSAP) was proposed, which would allow a single regulatory audit to satisfy the requirements of multiple regulatory authorities, thereby reducing the audit burden on manufacturers.

There was also an emphasis on the need for performance and clinical data for the pre-market control of Class B devices. This data is crucial to ensure the safety and effectiveness of these devices before they reach the market.

Certification to ISO 13485

Of the 287 respondents to the proposal to require ISO 13485:2016 standard to be met for Class B IVD devices:

- 142 (49%) supported the proposal
- 125 (44%) did not support the proposal
- 20 (7%) had no opinion

Comments from those who supported this proposal generally viewed ISO 13485:2016 as a robust standard that ensures excellent QMS practices. They believe it provides a comprehensive framework for manufacturers to ensure their products consistently meet both customer and regulatory requirements.

Comments from those who did not support this proposal expressed concerns about the adequacy of pre-market controls for Class B devices. Some respondents felt that ISO 13485:2016 might not be sufficient on its own to ensure the highest quality standards. They also highlighted the need for certain aspects of the standard to be clarified to prevent misinterpretation. Furthermore, the implementation of on-market surveillance was suggested to monitor devices, report incidents, and address any issues that arise post-market.

IVD devices and international reliance

The consultation invited views on whether, if the proposed approach is implemented, Class A and B IVD devices should be removed from the scope of international reliance.

Of the 287 responses received:

- 32 (11%) supported the proposal
- 102 (36%) did not support the proposal
- 153 (53%) had no opinion

Comments from those who supported this proposal generally noted that removal of Class A and B from the scope of international reliance would reduce confusion regarding conformity assessment requirements for manufacturers, and that self-declaration would be a faster option for Class B IVD devices in comparison to applying for a certificate of international reliance. They suggested that only having self-declaration UKCA requirements for these devices could also streamline international reliance applications for approved bodies, supporting focus on general medical devices and IVD devices with a higher classification.

Comments from those who did not support this proposal thought that the inclusion of Class A and B IVD devices within international reliance offered flexibility depending on available QMS certification and may reduce administrative burden and duplication for manufacturers. Some respondents suggested the inclusion could be a useful alternative

to UKCA, providing extra confidence for Class B IVD devices. There was also a preference for these devices to remain within international reliance when considering IVD device systems to reduce administrative burden. Others suggested that Class B IVD devices should be included within Route 1 of the international reliance scheme.

Government response

The majority of feedback received was largely supportive of a more risk proportionate system for IVD devices. Many stakeholders welcomed the initiative, recognising the potential for improved safety and effectiveness through tailored regulatory measures. We acknowledge the diverse feedback received regarding the proposal for Class B devices and the requirement to meet the ISO 13485:2016 standard. We appreciate the constructive comments and have considered them thoroughly in forming our response.

The government intends to amend the conformity assessment routes for IVD devices (including software IVD devices) in GB in line with the above proposal. We understand the concerns raised regarding UK-specific accreditation and the differing conformity assessment routes for NI and GB and so are taking active measures to address concerns, in line with the Government's commitment to protect the UK internal market. CE marked medical devices will continue to have a pathway to the GB market until 2028/30 and as detailed above, we will consult further in due course, on our approach to CE marked devices beyond this time. While acknowledging the concerns raised, it is only the conformity assessment route that differs (i.e. self assessment as opposed to third party assessment) and the technical requirements for Class B will be similar in both GB and NI. The MHRA will provide clear guidance to address these comments and we therefore do not expect this to affect the supply of products to Northern Ireland. To address any potential issues arising from differing conformity routes, the MHRA engaged with key stakeholders during the development of the Class B conformity route proposal. No additional concerns were identified.

The MHRA will also update its current guidance on software in IVD devices to provide clarity on the legislative changes.

We recognise the need for a reasonable transition period for these changes to IVD regulations. Manufacturers will have 5 years to adapt to the updated regulations in line with the transitional arrangements consulted on in 2021.

The government intends to proceed with the proposal to require UKCA declaration of conformity and QMS certification to ISO 13485 standard for Class B IVD devices. We

recognise the need for risk-proportionate controls on Class B devices to ensure their safety and performance. The government believes that QMS certification provides a robust framework for maintaining high-quality standards. However, we also acknowledge the concerns raised about the adequacy of pre-market controls and the potential for manufacturers to mis-classify products into Class B. To help mitigate this issue, if more than one classification could apply to an IVD device, the device will be required to be classified in the higher class.

To provide more flexibility and options for manufacturers, we will recognise QMS certification issued by International Accreditation Forum (IAF) accredited certification bodies from Comprehensive and Progressive Agreement for Trans-Pacific Partnership (CPTPP) countries as well as QMS certification issued by UKAS accredited bodies. This will help reduce trade barriers while maintaining high standards of certification. We will also specify in guidance the version of ISO 13485 standard that we will require compliance with.

We understand the benefits of the MDSAP in reducing the audit burden on manufacturers by allowing a single regulatory audit to satisfy multiple regulatory requirements. The MHRA is still exploring the feasibility of recognising MDSAP to streamline the regulatory process and support manufacturers, and a further update will be provided in due course.

The government acknowledges the importance of on-market surveillance to monitor devices, report incidents, and address any issues that arise post-market. To improve on-market surveillance, we introduced [The Medical Devices \(Post-market Surveillance Requirements\) \(Amendment\) \(Great Britain\) Regulations 2024](#) to ensure ongoing compliance and continuous improvement of IVD devices.

There was limited support for the proposal to remove Class A and B IVD devices from the scope of international reliance. Based on the feedback received, the government intends to keep these devices within the scope of international reliance (in Routes 1 and 3) to provide manufacturers with maximum flexibility regarding their regulatory strategy.

Our approach to revising the regulatory framework for IVD devices reflects a balanced consideration of stakeholder feedback, safety and performance. By implementing tailored measures, providing clear guidance and ensuring a reasonable transition period, we aim to support innovation while maintaining high patient safety standards.

Next steps

We are grateful for respondents' time in considering and providing views on all of our proposals. Following careful analysis of the responses, the MHRA will take forward legislative changes that reflect the results of this consultation.

The objectives set out in this document will be achieved by amending [The Medical Devices Regulations 2002](#). Amendments relating to international reliance and IVD devices will be taken forward in the 'Pre-Market' legislation currently being developed, which will be subject to World Trade Organization (WTO) notification requirements and brought into force as soon as Parliamentary time allows thereafter. We expect to publish the draft legislation on the WTO website later this year.

That legislation will also introduce the requirement to assign a UDI to a device; the transitional period for manufacturers to comply with that new requirement will be three years for general medical devices and five years for IVD devices. In the meantime, the MHRA will continue to develop separate legislation that will remove the requirement for a UKCA marking, which will come into force after the updated database is operational and the transitional period for the introduction of UDI has concluded.

Separately, we will prepare a consultation regarding the approach for CE marked medical devices. We will provide an update on this in due course. In the meantime, CE marked devices continue to be accepted in Great Britain until June 2028 or June 2030 ([depending on the specific device](#)).