Medicines & Healthcare products Regulatory Agency

Government response to the targeted consultation on indefinite recognition of CE marked medical devices

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Ministerial Foreword

One of this government's long-term missions is to create an NHS fit for the future, as outlined in the 10 Year Health Plan for England. Central to this is delivering three key shifts: from treatment to prevention, from hospital to the community and from analogue to digital.

Ensuring that patients and healthcare professionals have timely access to the medical devices they need is critical to delivering these three shifts. By ensuring rapid market access for new technologies, we can help treat patients more effectively, diagnose illness sooner, or prevent illness altogether.

This consultation sought views on the future approach to CE marked medical devices on the Great Britain market. The measures set out in this response build on our wider programme of reform to the regulatory framework for medical devices, including the development of international reliance routes and implementation of strengthened post-market surveillance.

The approach we are taking will help to maintain continuity of supply of safe and effective medical devices for patients and healthcare providers, while reducing unnecessary administrative burden for manufacturers. It also supports the Government's ambition, outlined in the Life Sciences Sector Plan, for the UK to be one of the top three fastest countries in Europe for access to MedTech by 2030.

Patient safety remains our priority. These measures will operate alongside strengthened post-market surveillance requirements, upcoming strengthened pre-market requirements and ongoing work to enhance oversight and enforcement. The Medicines and Healthcare products Regulatory Agency will remain responsible and accountable for monitoring the safety of all medical devices in the UK, regardless of their route to market.

I would like to thank all those who responded to this consultation. Your feedback has been invaluable in shaping our approach and will continue to inform the development of a regulatory system that supports patients, innovation and the NHS.

James Frith MP

Parliamentary Under-Secretary of State for Health Innovation

Executive Summary

This document sets out the government response to the targeted consultation on the indefinite recognition of CE marked medical devices in Great Britain (England, Wales, and Scotland). The consultation ran from 16 February 2026 to 10 April 2026 and received 1056 responses from a wide range of stakeholders, including medical device and in vitro diagnostic (IVD) device manufacturers, UK responsible persons, approved bodies, notified bodies, healthcare professionals, patient groups and individuals.

We invited views on three proposals:

- Extending the current transitional arrangements for devices that comply with the EU Medical Devices Directive 93/42 (EU MDD) to align with the EU timelines for devices to transition from EU MDD to the EU Medical Devices Regulation 2017/745 (EU MDR)
- Indefinitely recognising devices that comply with the EU MDR 2017/745 and EU in vitro Diagnostic Medical Devices Regulation 2017/746 (EU IVDR), and
- Introduction of an international reliance route for devices classified higher in Great Britain than in the EU.

A majority of respondents supported extending transitional timelines for EU MDD-compliant devices to align with EU deadlines, noting that this would prevent supply disruption and reduce unnecessary administrative burden.

A majority of respondents also supported the indefinite recognition of all CE marked devices certified under EU MDR and EU IVDR. Respondents noted that this approach would streamline access to innovative technologies, reduce duplicative regulatory processes and support growth in the UK MedTech sector. However, some stakeholders raised concerns regarding regulatory oversight, accountability and the UK's ability to independently assure safety and performance.

Most respondents did not support the introduction of a separate reliance route for devices classed higher in GB, noting that this would introduce a level of regulatory complexity that was disproportionate to any potential safety benefits.

Having considered the responses, the government intends to proceed with legislative changes to indefinitely recognise CE marked medical devices certified under EU MDR and EU IVDR, while aligning Great Britain transitional arrangements for EU MDD-compliant devices with EU timelines. This approach is intended to maintain continuity of supply, support ongoing patient access to safe and effective devices and reduce administrative burdens on manufacturers.

Manufacturers of CE marked devices placed on the Great Britain market will continue to be required to comply with certain domestic requirements, including appointment of a UK responsible person, MHRA registration, and post-market surveillance (PMS) obligations. The MHRA remains responsible for monitoring the safety of all medical devices in the UK, regardless of their route to market.

These changes form part of the wider programme to reform the UK medical devices regulatory framework, ensuring it remains proportionate, internationally aligned and supportive of both patient safety and innovation.

The proposed approach applies to the regulatory framework for Great Britain. For guidance on the regulation of devices in Northern Ireland, please refer to published guidance on the Regulation of devices in Northern Ireland. The indefinite recognition of the CE mark in Great Britain further supports the internal market and supply to Northern Ireland by ensuring that manufacturers can place the same product on the UK-wide market.

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.

As a transitional arrangement following EU exit, CE marked devices are recognised in Great Britain on a time-limited basis, meaning they can be placed on the Great Britain market without additional pre-market checks. Currently, CE marked devices may be placed on the Great Britain market until 30 June 2028 or 30 June 2030, depending on the device type and EU legislation it complies with.

Following the 2024-25 consultation on international reliance, UKCA marking and in vitro diagnostic devices, the government committed to consulting further on the long-term approach to recognition of CE marked devices. A recurring theme in the 2024-25 consultation responses was the request to indefinitely extend the recognition of CE marked medical devices in accordance with current transitional arrangements, where ‘recognition’ in this context means acceptance of CE marked medical devices on the Great Britain market without any additional domestic pre-market review.

This consultation therefore sought views on three proposals:

- Extending the current transitional arrangements for devices that comply with the EU Medical Device Directive 93/42 (EU MDD) to align with the EU timelines for devices to transition from EU MDD to the EU Medical Devices Regulation 2017/745 (EU MDR)
- Indefinitely recognising devices that comply with the EU MDR and EU in vitro Diagnostic Medical Devices Regulation 2017/746 (EU IVDR), and
- Introduction of an international reliance route for devices classified higher in Great Britain than in the EU.

Respondents

The consultation received 1056 responses, from those either responding on behalf of an organisation or as an individual sharing professional or personal views. Table 1 shows the breakdown of respondents based on whether they responded as an individual or on behalf of an organisation.

Table 1: Type of respondent

Type of respondent	Number of responses	Percentage of total responses
Organisation	406	38%
Individual sharing personal views	375	36%
Individual sharing professional views	271	26%
Did not specify	4	<1%

Those that responded on behalf of an organisation, or as individuals sharing professional views, were asked about the type of organisation they belong to. These 677 respondents represented a variety of sectors and interests, such as medical device and in vitro diagnostic (IVD) device manufacturers, UK responsible persons, approved bodies, notified bodies, healthcare professionals, and patient groups, with most responses being submitted by manufacturers. Table 2 shows the breakdown of the type of organisations that responded to the consultation.

Table 2: Type of organisation and number of responses

Type of organisation	Number of responses	Percentage of responses provided
Medical device/IVD device manufacturer	424	63%
UK responsible person	62	9%
Business	55	8%
Other	36	5%

Healthcare organisation	34	5%
Trade association	22	3%
Regulator	16	3%
Professional representative group	11	2%
Patient group	9	1%
Research organisation	8	1%

Those who responded as an organisation or as an individual sharing their professional views were asked to indicate where their organisation operates. The majority of those respondents operate in England, followed by locations outside of the UK, and then by locations within Scotland, Wales and Northern Ireland. Table 3 shows the breakdown of these locations.

Please note: respondents were able to select more than one location, or none at all.

Table 3: Locations of organisations

Location	Number of responses	Percentage of responses provided
England	170	55%
Outside the UK	121	39%
Scotland	11	4%
Wales	7	2%
Northern Ireland	1	<1%

Those who responded as individuals sharing personal views and experiences were asked where they live. The majority of the individuals sharing personal views were also based in England, followed by Scotland, locations outside the UK, and then by Northern Ireland and Wales. Table 4 shows the breakdown of respondent locations.

Table 4: Locations of individuals

Location of individuals	Number of responses	Percentage of responses provided
England	272	73%

Scotland	39	10%
I live outside the UK	25	7%
Northern Ireland	23	6%
Wales	16	4%

Those who responded as individuals sharing personal or professional views were asked if they were currently working as a clinical professional. The majority of individual respondents sharing personal or professional views did not identify as clinical professionals, followed by those responding “other” and those responding that they were clinical professionals. Those that responded with “other” included regulatory affairs professionals, former or retired clinical professionals, individuals working in MedTech, and individuals responding as patients. Table 5 provides a breakdown of the clinical professional status of individuals who responded sharing personal or professional views. Responses were not weighted based on clinical professional status.

Table 5: Clinical professional status of individual respondents

Clinical professional status	Number of responses	Percentage of responses provided
No	509	78%
Other	85	13%
Yes	55	9%

The consultation contained a question asking what ethnic group individuals belonged to. Following feedback received through the consultation, this question was removed on 10 March 2026 and the data not used.

Proposal 1

Background

As part of transitional arrangements following EU exit, in the Medical Devices Regulations 2002 (MDR 2002), general medical devices approved under EU MDD can be placed on the Great Britain market until **30 June 2028,** subject to meeting the relevant requirements in regulation 19B. After this date, in accordance with regulation 19C of the MDR 2002, general medical devices will have to comply with the EU MDR or undergo UKCA conformity assessment to be placed on the Great Britain market. The EU has extended the timelines for certain devices to transition to EU MDR until **31 December 2028**, leaving a six-month gap where some medical devices approved in the EU will not be eligible to access the Great Britain market.

The consultation proposed extending the current transitional arrangements for devices that comply with the EU MDD to align with the above EU transitional timelines. The aim is to prevent supply disruption between 30 June and 31 December 2028, while minimising unnecessary administrative burden for economic operators.

Feedback

Of the 1056 respondents to this proposal:

- 628 agreed with the proposal (60%)
- 374 disagreed with the proposal (35%)
- 54 had no opinion (5%)

Table 6 shows the breakdown of responses from organisations and individuals sharing their professional and personal views. Most of those who responded on behalf of organisations, as individuals sharing professional views, or did not specify were in favour of this proposal. Most of those who responded as individuals sharing personal views and experiences opposed this proposal.

Table 6. Responses by type of respondent

Respondent	Yes	No	No opinion
Organisations	335	40	31
Individuals sharing professional views	229	22	20
Individuals sharing personal views	61	311	3

Did not specify	3	1	0

Table 7 shows the breakdown of responses from organisations, broken down by organisation type. Those who responded on behalf of trade associations, medical device/IVD device manufacturers, UKRPs, businesses, professional representative groups, regulators, research organisations, healthcare organisations and “other” mostly supported this proposal. Those who responded on behalf of patient groups predominantly opposed this proposal. Where reasons were provided, they have been outlined below.

Table 7. Responses by organisation type

Respondent	Yes	No	No opinion
Trade Associations	21	1	0
Medical device/IVD device manufacturer	349	33	42
UKRP	54	6	2
Business	47	6	2
Patient group	1	7	1
Professional representative group	8	2	1
Regulator	14	0	2
Research organisation	7	1	0
Healthcare organisation	30	3	1
Other	33	3	0

Some respondents that agreed with the proposal highlighted a risk of supply disruption for medical devices still transitioning to EU MDR between 30 June and 31 December 2028 if the current timelines are maintained, which may hinder access for patients relying on these devices. Some respondents also highlighted that divergent timelines introduce significant additional regulatory complexity, the costs of which may be felt disproportionately by SMEs. Some respondents highlighted that this additional

regulatory burden would not bring clear benefits to patients in Great Britain, especially considering the extension would be relatively short.

Some respondents that disagreed with the proposal suggested that EU MDR is a more stringent regulation than EU MDD, and that the MHRA should be encouraging the transition to EU MDR. Some respondents also expressed opposition to any recognition of EU approved devices, arguing that all medical devices should be checked for compliance with MDR 2002, especially higher risk or implantable devices.

Proposal 2

Background

As part of transitional arrangements following EU exit, medical devices approved under EU MDR or EU IVDR can be placed on the Great Britain market until 30 June 2030, at the latest, subject to meeting relevant requirements under 19C (for general medical devices) or 44ZB (for in vitro diagnostic devices). After this date, CE marked devices will have to undergo UKCA conformity assessment to be placed on the Great Britain market.

The MHRA proposed indefinitely recognising devices that comply with the EU MDR and EU IVDR. The aim of this proposal is to streamline patient access to medical devices approved under EU MDR and IVDR while reducing administrative burdens for manufacturers and aligning requirements between Great Britain and Northern Ireland.

The MHRA also proposed indefinite recognition of these devices only when their risk class was the same, or lower in Great Britain. This proposal was intended to facilitate increased scrutiny and oversight over medical devices that the MHRA considers to be of higher risk than the EU.

Respondents that supported indefinite recognition for devices classed the same, or lower only, in Great Britain (“proposal 2b”) were directed to proposal 3. Proposal 3 is intended to complement a scenario where CE marked devices are recognised when they are classified the same, or lower, in Great Britain. Responses addressing proposal 2b and proposal 3 are considered together in the “Proposal 3” section.

Feedback

Of the 1056 respondents to this proposal:

- 608 agreed with the proposal to indefinitely recognise all CE marked devices (57%)

- 335 disagreed with the proposal (32%)
- 102 agreed with the proposal to indefinitely recognise CE marked devices classed the same, or lower, in Great Britain (10%)
- 11 had no opinion (1%)

Table 8 shows the breakdown of responses from organisations and individuals sharing their professional and personal views. Most of those who responded on behalf of organisations, or as individuals sharing professional views, were in favour of this proposal. Most of those who responded as individuals sharing personal views and experiences opposed this proposal.

Table 8: Responses by type of respondent

Respondent	Yes, for all devices	No	Yes, for devices which would be classified the same or lower in Great Britain	No opinion
Organisations	339	11	7	4
Individuals sharing professional views	213	13	44	1
Individuals sharing personal views	54	310	7	6
Did not specify	2	1	1	0

Table 9 shows the breakdown of responses from organisations, broken down by organisation type. Those who responded on behalf of trade associations, medical device/IVD device manufacturers, UKRPs, businesses, professional representative groups, regulators, research organisations, healthcare organisations and “other” mostly supported this proposal. Those who responded on behalf of patient groups mostly opposed this proposal.

Table 9: Responses by organisation type

Respondent	Yes, for all devices	No	Yes, for devices which would be classified the	No opinion

			same or lower in Great Britain	
Trade Associations	22	0	0	0
Medical device/IVD device manufacturer	365	3	54	2
UKRP	59	0	3	0
Business	51	0	4	0
Patient group	1	7	1	0
Professional representative group	5	1	4	1
Regulator	4	7	3	2
Research organisation	4	1	3	0
Healthcare organisation	21	1	11	1
Other	20	4	11	1

Some respondents that supported indefinite recognition for all CE marked medical devices highlighted that this would provide patients in Great Britain with streamlined access to medical devices, while also facilitating cross-UK supply and reducing administrative burden for manufacturers. The proposed additional Great Britain checks for devices assessed for the EU market were described as duplicative, with the associated costs having a disproportionately negative impact on SMEs. Some respondents highlighted that reducing regulatory burden for SMEs would have a positive impact on market competition and potentially lead to lower costs for the NHS. Some respondents also expressed that this would make the UK more attractive as a launch market for innovative products, promoting growth in the UK MedTech sector.

Some respondents that opposed indefinite recognition for CE marked medical devices expressed concerns around the degree of oversight the MHRA would have of CE marked medical devices in Great Britain if there were no additional pre-market checks

for CE-marked medical devices or Approved Body monitoring of PMS. Some respondents expressed concerns around how compliance with Great Britain PMS requirements would be monitored and manufacturers held to account, with uncertainty around who would review PMS reports/Periodic Safety Update Reports (PSURs) if there was no interaction with a UK approved body. Some respondents expressed concerns about sovereignty, as the UK government would have limited influence over future regulatory requirements in the EU.

Proposal 3

Proposal

In a scenario where CE marked medical devices are recognised only if they are classed **the same, or lower**, in Great Britain (as proposed in question 2b), devices classed higher in Great Britain would have to undergo a UKCA conformity assessment to be placed on the Great Britain market.

Respondents that supported proposal 2b were subsequently asked their views on proposal 3, which would introduce an international reliance route for devices that comply with the EU MDR and EU IVDR where the risk classification is **higher** under MDR 2002. The aim is to maintain streamlined Great Britain patient access to these devices and reduce administrative burden for manufacturers while providing additional regulatory oversight for devices that the MHRA considers higher risk. Whilst there is significant alignment between classification rules in Great Britain and the EU, some differences exist.

Feedback

10% (117) of respondents supported proposal 2b. When asked their views on proposal 3, which would introduce an international reliance route for devices that comply with the EU MDR and EU IVDR where the risk classification is higher under MDR 2002:

- 82 agreed with the proposal (70%)
- 18 disagreed with the proposal (15%)
- 18 had no opinion (15%)

Table 10 shows the breakdown of responses from organisations and individuals sharing their professional and personal views. Most of those who responded to this question were in favour of the proposal, regardless of whether they responded on behalf of an organisation or as an individual (except for those that did not specify their individual/organisational status, who were evenly split).

Table 10: Responses by type of respondent

Respondent	Yes	No	No opinion
Organisations	41	9	12
Individuals sharing professional views	33	5	6
Individuals sharing personal views	6	1	0
Did not specify	2	2	0

Table 11 shows the breakdown of responses from organisations, broken down by organisation type. Those who responded on behalf of medical device/IVD device manufacturers, UKRPs, businesses, patient groups, professional representative groups, research organisations, healthcare organisations and “other” mostly supported this proposal, while those who responded on behalf of trade associations mostly opposed this proposal. Those who responded on behalf of regulators were evenly split.

Table 11: Responses by organisation type

Respondent	Yes	No	No opinion
Trade Associations	0	4	0
Medical device/IVD device manufacturer	40	5	13
UKRP	4	0	0
Business	2	1	1
Patient group	1	0	0
Professional representative group	4	0	0
Regulator	2	2	1
Research organisation	3	0	0
Healthcare organisation	11	0	0

Other	7	2	3

Some respondents that supported this proposal described it as a balanced approach that would provide the benefits of recognition while providing additional oversight for devices that the MHRA considers to be a higher risk class than the EU.

Some respondents that did not support this proposal expressed concerns that this approach would introduce regulatory uncertainty and complexity that would complicate supply chains and make long-term business planning more difficult. Some respondents suggested that these additional regulatory burdens would be disproportionate to any patient safety benefits that this additional route would provide, considering the number of devices affected would be small. Some respondents suggested that the reliance step may not be sufficient to provide safety assurances as approved bodies would be reviewing data for devices that they did not initially certify, which may prove difficult. Some respondents suggested that Great Britain should align its classification rules with the EU, which would remove the need for a separate reliance route.

Government response

Having considered the views of all respondents, the government intends to take forward Proposal 1 and 2a, reflecting the views of a majority of respondents:

- Proposal 1: The government intends to align the timelines for recognising devices approved under EU MDD with the EU timelines for devices to transition to EU MDR, so these devices will be accepted until the end of the EU transition period (currently, 31 December 2028), maintaining the requirements set out in regulation 19B of MDR 2002. In addition, EU MDD-certified medical devices placed compliantly on the EU or Great Britain market prior to the end of the EU transitional arrangements will continue to be allowed on the Great Britain market, mirroring the approach taken in the EU.

- Proposal 2a: The government intends to indefinitely recognise all CE marked medical devices certified under EU MDR and EU IVDR, in line with Proposal 2a, maintaining the requirements set out in regulations 19C, 30A and 44ZB of MDR 2002.

To prevent unnecessary regulatory complexity, the government does not intend to take forward Proposals 2b and 3, which together would introduce a separate reliance route based on divergent classification.

For combination products regulated as medical devices in MDR 2002, including devices incorporating an ancillary medicinal substance, the device component would continue to be eligible for market access under proposal 2a, though they may still need to meet certain requirements under the Human Medicines Regulations 2012.

These proposals are anticipated to provide continued patient access to medical devices, while reducing the administrative burden on medical device manufacturers who already comply with EU regulations by reducing regulatory complexity and duplicative checks. Furthermore, it will support convergence across the United Kingdom, where devices must bear the CE mark for Northern Ireland, which continues to apply certain EU regulations in order to maintain dual market access to the UK internal market and the EU single market. It also represents a continuation of our current approach that has been in place for several years, providing clarity and certainty for manufacturers and other economic operators.

For Proposal 2a, some respondents raised concerns around patient safety and compliance. The MHRA places requirements on manufacturers of CE marked devices

to help ensure any safety and compliance risks are mitigated as much as possible, including requirements:

- To comply with strengthened PMS requirements that came into force in June 2025, facilitating quicker reporting of serious incidents by device manufacturers and enhanced and proactive reporting of device usage throughout their lifetime.
- For manufacturers based outside the UK, to appoint a UK responsible person (UKRP) who is responsible for the manufacturer's devices on the UK market, supporting compliance and enforcement.
- For manufacturers (or their UKRP) placing CE marked devices on the Great Britain market, to continue to register their devices with the MHRA, helping ensure compliance with product safety and medical devices regulations.
- To ensure that technical documentation and the certificate of conformity is prepared and made available in English.
- To comply with enforcement notices issued under the Medicines and Medical Devices Act 2021 (MMD Act 2021) (i.e., compliance, suspension, safety and information notices). The MMD Act 2021 empowers the MHRA to act on safety concerns, including by restricting or suspending devices when necessary to protect public health.

These requirements help to ensure that manufacturers actively identify and mitigate safety risks throughout the lifecycle of their devices when they are placed on the UK market.

As well as placing requirements on manufacturers, the MHRA undertakes activities to enhance the safety of medical devices and monitor device performance, including:

- Implementing the recommendations of the Independent Medicines and Medical Devices Safety (IMMDS) Review to strengthen device safety.
- Investigating allegations of non-compliance and adverse events for CE and UKCA marked devices.
- Promoting reporting through the Yellow Card scheme to patients and healthcare professionals.
- Working with international partners to exchange information on safety signals.
- Publishing medical device safety information following MHRA investigations.

The MHRA will undertake a range of market surveillance activities to help ensure that CE marked devices available in GB are safe and compliant, for example through proactive market surveillance, investigation of emerging concerns and taking enforcement action where necessary.

The MHRA also intends to consider how market surveillance, compliance and enforcement can be further optimised to help ensure that the MHRA has proportionate oversight over medical devices in the UK.

Manufacturers of UKCA marked medical devices will continue to be able to supply their products in Great Britain, and the UKCA mark will remain available as a route to market access alongside continued recognition of CE marked devices. The MHRA is currently undertaking work to help ensure the domestic route to market remains fit for purpose long term.

Concerns from individuals harmed by pelvic mesh

The MHRA received significant representation from respondents who have been harmed by pelvic mesh, most of whom opposed the proposals to indefinitely recognise devices approved under EU devices regulations and extend recognition of EU MDD certified devices.

The government greatly appreciates the time taken by respondents and acknowledges the terrible experiences of individuals who have suffered immensely following procedures with pelvic mesh. The government acknowledges that these experiences have negatively impacted the trust in the use of certain medical devices, and we are committed to listening and restoring trust with patients and the public by reforming the medical device regulations, implementing the recommendations from the IMMDS Review.

The government is taking measures, broadly aligned with requirements under the EU MDR and EU IVDR, with which manufacturers of CE marked devices will have to demonstrate compliance, including:

- Implementation of strengthened PMS requirements, including for CE marked devices.
- The formulation of “pre-market” legislation for UKCA marked devices, which will contain measures to improve the traceability of implanted devices including use of Unique Device Identifiers (UDI) and implant cards, as well as increasing the classification of implantable devices to ensure they receive the highest scrutiny throughout their lifetime.

There is currently a pause on the use of vaginal mesh for stress urinary incontinence and pelvic organ prolapse. This pause remains in place pending the fulfilment of certain

patient safety criteria. This means that these products are only used as a last resort through a high-vigilance programme of restricted practice.

Next steps

We are grateful for all respondents' time in considering and providing views on all our proposals. Following careful analysis of the responses, the MHRA will introduce legislative changes that reflect proposals 1 and 2a of this consultation. Subject to parliamentary approval, these legislative changes will be made prior to the end of the earliest relevant transition period, which is 30 June 2028.

While the regulatory framework applies across Great Britain, health is a devolved matter. The UK government intends to continue our engagement with devolved governments and the NHS across the UK as the MHRA develops the future regulatory regime to understand their impacts across the UK.