Medicines & Healthcare products Regulatory Agency

Medical devices regulations: targeted consultation on the indefinite recognition of CE marked devices

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Contents

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. Critical to this mission is facilitating three shifts, moving from treatment to prevention, hospital to the community, and analogue to digital.

Critical to delivering all three shifts will be ensuring that patients and healthcare professionals have access to the medical devices they need as quickly and safely as possible. By ensuring rapid market access for new technologies, we can help treat patients more effectively, diagnose illness sooner, or prevent illness altogether.

The proposed measures in this consultation will complement the wider reforms we are making to the regulatory framework for medical devices, particularly the international reliance scheme, which will enable swifter market access for certain devices that have already been approved in a comparable regulator country.

By safeguarding patient access to medical devices, these proposals support the Government ambition, outlined in the Life Sciences Sector Plan, for the UK to become one of the top three fastest countries in Europe for access to MedTech by 2030.

Patient safety remains a key priority. These reforms will operate alongside the MHRA's pre-market reforms and the strengthened post-market surveillance regime to improve the safety and performance of medical devices throughout their lifecycle.

Dr Zubir Ahmed

Parliamentary Under-Secretary of State for Health Innovation and Safety

Executive summary

This consultation applies to general medical devices, active implantable medical devices (AIMDs) and in vitro diagnostic (IVD) devices for Great Britain (GB) (England, Scotland, and Wales). For guidance on the regulation of devices in Northern Ireland, refer to the regulation of devices in Northern Ireland.

Following EU Exit, the government put in place legislation that amends the Medical Devices Regulations 2002 (SI 2002 No 618, as amended) (MDR 2002) to extend the acceptance of CE marked devices on the Great Britain market until June 2030, at the latest. This was to support the ongoing supply of medical devices to Great Britain and ease the transition to the future regulatory framework for medical devices.

In July 2025, the MHRA published the government response to the public consultation on routes to market and in vitro diagnostic devices. This consultation set out several 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 (including for CE marked medical devices).

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, where ‘recognition’ in this context means acceptance of CE marked medical devices on the Great Britain market without any domestic pre-market review. The Government committed to consulting on indefinite recognition of CE marked medical devices in its response to the consultation.

We are seeking views from stakeholders regarding:
1. Extending the current transitional arrangements for devices that comply with the EU Medical Device Directive (MDD) to align with the EU timelines for devices to transition from MDD to EU Medical Device Regulation (EU MDR).

2. Indefinitely recognising devices that comply with the EU MDR and EU In Vitro Diagnostic Medical Devices Regulation (EU IVDR).

3. Introducing an international reliance route for devices that comply with the EU MDR and EU IVDR where the device classification is higher under the MDR 2002.

Introduction

The Medicines and Healthcare products Regulatory Agency (MHRA) is the regulator of medicines, medical devices and blood components for transfusion in the UK. The MHRA is responsible for ensuring that medical devices are safe and perform as intended for patients.

Medical devices are products 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 legal definitions of medical devices and in vitro diagnostic devices are described in Annex A.

Medical devices are sorted into different classes, depending on the risk they pose to patient and public health. For general medical devices, these are:

- Class I: lowest risk e.g., syringes without needles, spectacle frames, standard adhesive bandages, examination lights
- Class IIa: e.g., short-term corrective contact lenses, suture needles, standard hearing aids, TENS devices
- Class IIb: e.g., apnoea monitors, ventilators, surgical lasers, diagnostic X-ray sources
- Class III: e.g., highest risk e.g. pacemakers, total hip joint replacement system, breast implants, contraceptive IUDs, devices containing medicinal substances

IVD devices are used to analyse samples from the human body, such as blood or urine, to provide information on health conditions or diseases. Under the current MDR 2002, IVD devices are classified using a list-based classification system based on their impact on patient and public health. The current risk classes are as follows:

- General IVD devices: i.e., all IVD devices other than those listed below
- IVDs for self-testing (a device intended by the manufacturer to be able to be used by lay persons in a home environment) excluding self-test devices covered below
- IVDs in the classifications stated in Part IV of the MDR 2002, Annex II List B (as modified by Part III of Schedule 2A to the MDR 2002) which, among others, includes reagents products for rubella, toxoplasmosis and phenylketonuria as well as devices for self-testing for blood sugar

- IVDs in the classifications stated in Part IV of the MDR 2002, Annex II List A (as modified by Part III of Schedule 2A to the MDR 2002) which includes reagents and products for HIV I and II, hepatitis B, C and D, and reagent products for determining ABO systems

In its response to the 2024 consultation on international reliance, UKCA marking and in vitro diagnostic devices, the MHRA committed to amending the IVD device classification system to align with the principles developed by the International Medical Device Regulators Forum (IMDRF). This approach will introduce four classes: A, B, C, and D, with Class A being the lowest risk and Class D being the highest.

At the MHRA, we put 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 safe and effective. We want to develop a future regime for medical devices that enables:

- improved patient and public safety;
- innovation and growth;
- close alignment with international best practice; and
- risk proportionate regulation of medical devices.

There is a statutory requirement to consult publicly before amending any regulations under the Medicines and Medical Devices Act 2021. Your feedback will help us to refine and improve the proposed framework, and to assess its impact on patients, healthcare systems, the medical devices sector and other stakeholders.

The MHRA is inviting members of the public – including patients, medical device researchers, developers, manufacturers and suppliers, approved bodies, clinicians and other healthcare professionals – to provide their views on proposed changes to the regulatory framework for medical devices that will help us meet these objectives.

The legal basis and the assessment of the matters set out in the Medicines and Medical Device Act section 15 are described in Annex C.

What is this consultation about?

We are seeking views on the long-term approach for CE marked medical devices on the Great Britain (GB) market, to ensure there is no interruption to the supply of medical devices for patients and the public. Previous milestones related to the availability of CE marked medical devices on the GB market are summarised in the following timeline.

Before January 2021 All medical devices on the GB market were CE marked.

The MHRA and EU competent authorities designated notified bodies and conducted market surveillance within their jurisdictions.

After January 2021 Post EU exit

The MHRA does not designate, or monitor, notified bodies for CE marked medical devices. This is being performed by the EU competent authorities.

There is no information sharing agreement between MHRA and EU entities, such as competent authorities and notified bodies, to enable routine sharing of safety concerns regarding CE marked medical devices on the GB or EU market. However, the MHRA engages with the EU through the Windsor Framework, the Trade and Cooperation Agreement and international forums such as the International Medical Device Regulators Forum to share regulatory information in the interest of patient safety.

May 2021/May 2022 EU MDR and IVDR came into effect in the EU

The EU MDR and IVDR were introduced with the aim to improve device safety, quality and performance. They also increased the role of notified bodies in conformity assessment and post market surveillance for general medical devices and in vitro diagnostic devices.

March 2023 Transitional provisions for EU MDR and IVDR were extended in the EU

The EU MDR and IVDR were amended through Regulation (EU) 2023/607 to give manufacturers and notified bodies more time to carry out conformity assessments in accordance with the new requirements. This was to protect public health and avoid shortages of medical devices.

Jan 2023 – July 2025 Policy development for international reliance in GB

The MHRA developed proposals for international reliance with trusted advisors from approved bodies, industry, trade associations, healthcare professionals, patient groups and other regulators.

The proposals included a streamlined approved body review for CE marked medical devices, relying on assessments that have already been performed in the EU by notified bodies.

The consultation invited public feedback on these proposals. The government published its response to the consultation, highlighting general support for reliance and many requests from industry to indefinitely extend the recognition of CE marked medical devices in GB instead. The government committed to consulting further on this.

January 2021 UKCA marking was introduced in GB

The MHRA introduced the process for UKCA marking of medical devices, including a designation process for approved bodies to assess conformity of medical devices against MDR 2002.

At the same time, transitional arrangements were introduced that extend the acceptance of CE marked devices on the GB market until 30 June 2023 to support the transition to UKCA and support the movement of goods in the UK Internal Market.

May 2023 Transitional arrangements for CE marked devices were extended in GB

In accordance with the EU update, transitional arrangements in GB were extended so that CE marked devices may continue to be placed on the GB market until 30 June 2028 or 30 June 2030, depending on the device and EU legislation complied with. This was to protect public health and avoid shortages and supply interruptions of medical devices.

June 2025 Post-market surveillance regulations come into effect in GB

The Medical Devices (Post-market Surveillance Requirements) (Amendment) (Great Britain) Regulations 2024 amended the MDR 2002 to enhance reporting obligations for manufacturers to support early detection of safety issues for all devices on the GB market, including CE marked devices.

Present (2025) Current market status in GB

Most manufacturers have delayed transitioning to UKCA while the international reliance scheme was developed. As a result, approximately 90% of medical devices on the GB market remain CE marked today.

Throughout this consultation, proposals for recognition and reliance are discussed. We are aligned with the definitions from the World Health Organization, where:

- ‘Recognition’ is the acceptance of the regulatory decision of another regulator or trusted institution. Recognition should be based on evidence that the regulatory requirements of the reference regulatory authority are sufficient to meet the regulatory requirements of the relying authority.

- ‘Reliance’ is the act whereby the regulatory authority in one jurisdiction takes into account and gives significant weight to assessments performed by another regulatory authority or trusted institution, or to any other authoritative information, in reaching its own decision. The relying authority remains independent, responsible and accountable for the decisions taken, even when it relies on the decisions, assessments and information of others.

The Medical Devices Regulations 2002 (MDR 2002) applies to GB only, as, under the terms of the Windsor Framework Agreement, Northern Ireland (NI) applies the EU MDR and EU IVDR, with MHRA acting as Competent Authority for NI. This allows NI to maintain its dual market access to both the UK Internal Market and EU Single Market without additional requirements or paperwork, as is the case now. Therefore, these proposals would only apply in GB, however indefinite recognition of CE marked medical devices in GB may also benefit stable continued supply to NI.

Background

1. Devices that comply with the EU Medical Device Directive

The EU Medical Device Directive 93/42 (MDD) was established in 1993 and was replaced by the EU Medical Devices Regulation 2017/745 (EU MDR). The EU MDR was adopted in April 2017 and came into force in May 2021. The EU MDR aims to improve the safety and performance of medical devices.

Regulation 19B of the MDR 2002 describes the requirements for accepting CE marked general medical devices that have undergone conformity assessment under the MDD.

This regulation is a transitional arrangement that will end on **30 June 2028** under the current arrangements. After this date, general medical devices that have undergone conformity assessment in the EU will have to comply with the EU MDR, per regulation 19C, to be placed on the GB market under existing transitional arrangements, or they have to undergo UKCA conformity assessment.

The EU set out timelines for medical devices to transition from MDD to EU MDR, and these have been extended for certain devices (including Class IIb (with exceptions[1]), Class IIa, and Class I sterile or measuring devices under MDD) until **31 December 2028.**

This means that, under existing transitional arrangements, there will be a period of approximately six months where devices still accepted in the EU and Northern Ireland (under MDD) will not be eligible to access the GB market (unless they are qualifying Northern Ireland goods). Table 1 provides a summary of the transitional timelines for devices approved under MDD.

MDD classification	Can be placed on the EU market under MDD until	Can be placed on the GB market under MDD until	Example devices
Class I (self-declaration)	26 May 2021	26 May 2021	Walking aid
Class I (measuring)	31 December 2028	30 June 2028	Thermometer
Class I (sterile)	31 December 2028	30 June 2028	Sterile bandage
Class IIa	31 December 2028	30 June 2028	Hearing aid
Class IIb (non-implantable)	31 December 2028	30 June 2028	Ventilator
Class IIb (implantable "Well established Technologies device")*	31 December 2028	30 June 2028	Bone fixation screw
Class IIb (implantable)	31 December 2027	31 December 2027	Peripheral stent
Class III	31 December 2027	31 December 2027	Total joint replacement

Table 1: The current timelines for placing devices approved under MDD on the EU and GB markets, depending on risk classification, with examples. Rows highlighted in purple indicate where devices approved under MDD may be placed on the EU market for longer than the GB market. * See footnote 1.

2. Devices that comply with the EU Medical Device Regulation and EU In Vitro Diagnostic Medical Device Regulation

[1] Class IIb implants are excluded from the EU transitional arrangements extension, with the exception of class IIb implants that are "certain WET devices". "WET" means Well Established Technologies, and refers to sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips and connectors, see Article 120(3a)(a) in the EU MDR.

Regulations 19C and 44ZB of MDR 2002 describe the requirements for accepting CE marked medical devices that have undergone conformity assessment under EU MDR and EU IVDR respectively.

These regulations are transitional arrangements that will end on **30 June 2030,** at the latest, per the current arrangements. This means that, after this date, CE marked devices will no longer be accepted in GB and UKCA marking will be required. Devices approved in the EU would still need to comply in full with the MDR 2002, including undergoing conformity assessment by a UK approved body[2] to access the GB market or international reliance if they are used in a comparable regulator country.

Annex XVI of EU MDR includes provisions for products without an intended medical purpose, but with a similar function and risk profile to medical devices, such as dermal fillers and coloured contact lenses. Products without an intended medical purpose are not currently in scope of the MDR 2002 and therefore are not in scope of the current transitional provisions or the proposals outlined in this consultation.

Proposals

Proposal 1. Extend the current GB transitional arrangements for devices that comply with the EU Medical Device Directive to align with the transitional timelines published by the EU

We propose to extend the current transitional arrangements in Regulation 19B to align with published transitional timelines in the EU to minimise any risk of device supply disruption.

This would mean that devices approved under MDD, which would likely be in the process of transitioning to EU MDR, could be placed on the GB market until **31 December 2028,** as opposed to **30 June 2028** under the current transitional arrangements**.**

The proposal intends to align this timeline with the EU, so that if transitional arrangements are extended further in the EU, medical devices with a valid CE certificate can still be placed on the GB market if they meet the transitional arrangements within the MDR 2002 (which would be updated accordingly if this proposal is accepted).

[2] Approved bodies are organisations that have been designated by the MHRA to assess the conformity of medical devices and confirm that they meet the requirements in MDR 2002 that apply to them.

Proposal 2. Indefinitely recognise devices that comply with the EU Medical Device Regulation and EU In Vitro Diagnostic Medical Device Regulation

This proposal is to extend the transitional arrangements in Regulations 19C and 44ZB indefinitely for devices which comply with the EU MDR or IVDR. The MHRA would like to hear your views regarding whether this should be:

(a) for **all** devices, or
(b) only for those which are classified as the **same, or lower,** risk category under MDR 2002 as they are in the relevant EU device regulations.

Devices that are recognised under this proposal would continue to be placed on the GB market without additional checks by an approved body. This would reduce the risk of interruption to the supply of medical devices for patients in GB.

Manufacturers (or their UK responsible person) would continue to register their devices with the MHRA, meet the registration requirements in the MDR 2002, and comply with the PMS requirements in the MDR 2002. These requirements came into force in 2025, and include notification requirements for incidents and field safety corrective actions taking place after the device is first approved for the GB market.

Manufacturers (or their UK responsible person) would need to notify the MHRA if the EU MDR or IVDR certificate is withdrawn or suspended in the EU and in these cases would need to stop placing the relevant devices on the GB market.

The MHRA defines classification rules to align with the risk level of the device and needs of the GB population, which may sometimes require a higher risk classification than in the EU to facilitate additional pre-market scrutiny and post-market surveillance for patient safety.

Whilst there is significant alignment between classification rules in GB and the EU, some differences exist. An alternative option for this small proportion of devices with a higher risk classification in GB is discussed in the next proposal.

Through the indefinite recognition for **all** CE marked devices, it would mean that the classification rules in the EU MDR or IVDR would be accepted in GB, whereas selecting indefinite recognition for CE marked devices which are classified as the **same, or lower,** risk category in GB would mean that the GB classification rules would apply and take precedence over the EU classification rules in cases where the device classification is higher under MDR 2002.

Accepting this proposal would mean there would continue to be no ongoing approved body oversight of these devices once placed on the GB market in relation to the MDR 2002, including certain PMS requirements in GB. Instead, the devices would have undergone a

review by an EU notified body[3] prior to being placed on the GB market and would continue to be monitored by an EU notified body against EU regulations. The MHRA currently do not have access to information that notified bodies hold on CE marked devices that are then placed on the market in GB, such as surveillance audits, supplier monitoring, and technical file review outputs. This means the MHRA may take more time to process investigations for CE marked devices in GB, meaning that recalls or corrections may happen slower. The MHRA engages with the EU through the Windsor Framework, the Trade and Cooperation Agreement and international forums such as the International Medical Device Regulators Forum (IMDRF) to share regulatory updates and information in the interest of patient safety and harmonisation.

To ensure the MHRA has proportionate oversight of all medical devices on the GB market, regardless of its route to market, the MHRA are considering changes related to market surveillance, compliance and enforcement in the future. This may include, for example, additional requirements for manufacturers and their UK responsible person (if there is one) to provide information to the MHRA, upon request. The MHRA will provide further detail on this in due course, depending on the outcome of this consultation. Any further related proposals would be subject to public consultation, including any relevant fees if applicable.

If you agree with this proposal only for those devices which are classified as the **same, or lower,** risk category under MDR 2002 as they are in the relevant EU device regulations, then proceed to Proposal 3.

Please note that if this proposal is rejected, then the previously proposed international reliance routes for CE marked devices would be introduced instead due to receiving positive support in the previous public consultation.

Proposal 3. Introduce an international reliance route for devices that comply with the EU Medical Device Regulation and EU In Vitro Diagnostic Medical Device Regulation where the risk classification is higher under MDR 2002.

For the small proportion of devices that would be classified **higher** under the classification rules in MDR 2002 than in the EU MDR or EU IVDR, this proposal will introduce an international reliance route. The eligibility criteria for this route and the requirements that would apply are set out in set out in Annex B.

[3] A notified body is a third-party organisation designated by an EU member state (or other countries under specific agreements) to assess the conformity of certain products with EU regulations before being placed on the EU market.

Manufacturers of these devices would be able to use the current transitional arrangements until 30 December 2030. After this date, they could continue to access the GB market using this international reliance route or the UKCA conformity assessment process.

Some devices which can self-declare as Class I in the EU could be classified as Class IIa under MDR 2002, and these would not be eligible for this route (as explained in Annex B).

Questions

C1. Do you agree with proposal 1, which would extend the current transitional arrangements for devices that comply with the EU Medical Device Directive to align with the transitional timelines published by the EU?

Yes (include short explanatory text if appropriate)

No (include short explanatory text if appropriate)

No opinion

C2. Do you agree with proposal 2, which would indefinitely recognise devices that comply with the EU Medical Device Regulation and EU In Vitro Diagnostic Medical Device Regulation?

Yes, for **all** devices (include short explanatory text if appropriate)

Yes, for devices which would be classified the **same, or lower,** in GB (using the classification rules specified in the MDR 2002)? (include short explanatory text if appropriate and then proceed to Question C3)

No (include short explanatory text if appropriate)

No opinion

C3. Do you agree with proposal 3, which would introduce an international reliance route for devices that comply with the EU Medical Device Regulation and EU In Vitro Diagnostic Medical Device Regulation where the risk classification is higher under MDR 2002?

Yes (include short explanatory text if appropriate)

No (include short explanatory text if appropriate)

No opinion

Demographic Questions - About you

D1A. In which capacity are you primarily responding to this survey?

a. An individual sharing my personal views and experiences

b. An individual sharing my professional views

c. On behalf of an organisation

[if selected D1A.a. or b.] D1B. Are you currently working as a clinical professional? Which of the below describes you best?

a. No, I'm not a clinical professional

b. Yes, I'm a [free text box with 50 character limit]

c. Other (please specify)

[if selected D1A.b. or D1A.c.] D1C. Which of the below describes your organisation best?

a. Trade Association

b. Medical device/IVD device manufacturer

c. UK Responsible Person

d. Business

e. Patient or Patient group

f. Professional representative group

g. Regulator

h. Research organisation

i. Healthcare organisation

j. Other (please specify)

[if selected D1A.b. or c.] D1D. Which parts of the UK and other global markets do you currently supply?

a. [free text box with 200 character limit]

[if selected D1A.a] D2A. Where do you live in the UK?

a. England

b. Northern Ireland

c. Scotland

d. Wales

e. I live outside the UK

[if selected D1A.b or D1A.c] D2B. Where does your organisation operate? (Please tick all that apply)

a. England

b. Scotland

c. Wales

d. Northern Ireland

e. Outside the UK

[if selected D1A.a. or b.] D2C. What is your ethnic group?

a. Any other Asian background

b. Any other Black/African/ Caribbean background

c. Any other ethnic group

d. Any other mixed ethnic background

e. Asian/Asian British – Bangladeshi

f. Asian/Asian British – Chinese

g. Asian/Asian British – Indian

h. Asian/Asian British – Pakistani

i. Black/African/Caribbean/Black British – African

j. Black/African/Caribbean/Black British – Caribbean

k. Mixed ethnic group – White and Asian

l. Mixed ethnic group -White and Black African

m. Mixed ethnic group – White and Black Caribbean

n. Not Known

o. Other ethnic group – Arab

p. Prefer not to say

q. White – Any other White background

r. White – English/Welsh/Scottish/Northern Irish/British

s. White – Gypsy or Irish Traveller

t. White - Irish

[if selected D1A.b or D1A.c] D2D. How many employees does your organisation employ? An employee is anyone aged 16 years or over that an organisation directly pays from its payroll(s), in return for carrying out a full-time or part-time job or being on a training scheme. It excludes voluntary workers, self-employed and working owners who are not paid via PAYE.

a. 0-9

b. 10-49

c. 50-249

d. 250-499

e. 500+

f. Don't know

[if selected D1A.b, D1A.c, or D1A.g] D2E. Does your business produce or supply any of the following products?

a. Medicines

b. Medical devices

c. In vitro diagnostic Medical Devices

d. Borderline substances (e.g. medical nutrition)

e. None of the above [exclusive]

f. Don't know [exclusive]

Satisfaction survey - give feedback on participating

Instruction text - If you do not wish to leave your feedback, please select the 'Submit' button.

S1. It was easy to participate in this opportunity

a. Strongly agree

b. Agree

c. Neither agree or disagree

d. Disagree

e. Strongly disagree

S2. The supporting information was understandable

a. Strongly agree

b. Agree

c. Neither agree or disagree

d. Disagree

e. Strongly disagree

S3. What could we do better?

Free text box

Data protection notice

This consultation seeks the views of individuals and organisations through a public consultation, to inform amendments to the Medical Devices Regulations 2002.

This notice sets out how data collected through this call for evidence will be used and respondents' rights under Articles 13 and/or 14 the UK General Data Protection Regulation (GDPR). If you require any further information about how the MHRA processes your data, please see the MHRA privacy notice.

Data controller

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

What personal data we collect

You can respond to the consultation through our public survey, which can be completed online. Alternatively, you can download the form, complete it and send this to us by email.

We will collect data on:

- whether you are responding as an individual or on behalf of an organisation;
- your occupation;
- the country and region you live in, or where your organisation provides services in the UK; and
- your ethnic group, if provided.

If volunteered by you, we will also collect data on:

- your email address (if completing a paper survey and submitting it by email, or if responding on behalf of an organisation and confirming MHRA can contact you about your response); and
- any other personal data you volunteer by way of evidence or example in your response to open-ended questions in the survey.

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 consultation 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 are responding on behalf of an organisation and 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 consultation will be seen by:

- Professionals within MHRA who are working on this consultation.

- MHRA's third-party supplier (SurveyOptic), 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 consultation

• International data transfers and storage locations

Storage of data by 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 MHRA for 3 years and disposed of sooner if possible.

SurveyOptic will securely erase the data held on their system 5 years after the call for evidence 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

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

SurveyOptic is Cyber Essentials certified.

Your rights as a data subject

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

These rights are:

- the right to get copies of information – individuals have the right to ask for a copy of any information about them that is used;

- the right to get information corrected – individuals have the right to ask for any information held about them that they think is inaccurate, to be corrected;

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

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

- the right to get information deleted – this is not an absolute right, and continued use of the information may be necessary, with individuals being advised if this is the case.

Comments or complaints

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

Data Protection Officer
MHRA
10 South Colonnade
London
E14 4PU

Anyone who is still not satisfied can complain to the Information Commissioner's Office. Their website address is www.ico.org.uk and their postal address is:

Information Commissioner's Office
Wycliffe House
Water Lane
Wilmslow

Cheshire
SK9 5AF

Produced by the Medicines and Healthcare products Regulatory Agency.
www.gov.uk/mhra

Annex A: Legal definitions

Medical devices are defined in regulation 2(1) of the UK Medical Devices Regulations 2002 (as amended), as follows:

“medical device” means any instrument, apparatus, appliance, software, material or other article, whether used alone or in combination, together with any accessories, including the software intended by its manufacturer to be used specifically for diagnosis or therapeutic purposes or both and necessary for its proper application, which—

(a) is intended by the manufacturer to be used for human beings for the purpose of-

(i) diagnosis, prevention, monitoring, treatment or alleviation of disease,

(ii) diagnosis, monitoring, treatment, alleviation of or compensation for an injury or handicap,

(iii) investigation, replacement or modification of the anatomy or of a physiological process, or

(iv) control of conception; and

(b) does not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means, even if it is assisted in its function by such means,

and includes devices intended to administer a medicinal product or which incorporate as an integral part a substance which, if used separately, would be a medicinal product and which is liable to act upon the body with action ancillary to that of the device.

“active implantable medical device” means a medical device which—

(a) relies for its functioning on a source of electrical energy or a source of power other than that generated directly by the human body or by gravity; and

(b) is intended to be totally or partially introduced into the human body (whether surgically or medically, including being introduced into a natural orifice) and which is intended to remain in the human body after completion of the surgical or medical procedure during which it is introduced,

even if it is intended to administer a medicinal product or incorporates as an integral part a substance which, if used separately, would be a medicinal product.

“in vitro diagnostic medical device” means a medical device which—

(a) is a reagent, reagent product, calibrator, control material, kit, instrument, apparatus, equipment or system, whether used alone or in combination; and

(b) is intended by the manufacturer to be used in vitro for the examination of specimens, including blood and tissue donations, derived from the human body, solely or principally for the purpose of providing information—

(i). concerning a physiological or pathological state,

(ii). concerning a congenital abnormality,

(iii). to determine the safety and compatibility of donations, including blood and tissue donations, with potential recipients, or

(iv). to monitor therapeutic measures,

and includes a specimen receptacle but not a product for general laboratory use, unless that product, in view of its characteristics, is specifically intended by its manufacturer to be used for in vitro diagnostic examination.

Annex B: International reliance

To be eligible for the international reliance access route in proposal 3, the medical devices must:

- be within the scope of the Medical Devices Regulations 2002;
- be classified in accordance with Medical Devices Regulations 2002;
- have English language labelling and packaging;
- comply with GB requirements for all other relevant product requirements such as those for machinery, electronics compatibility, units of measurement, and labelling materials of concern where applicable;
- have a UK Responsible Person, the name and address of which would be included on the product labelling or the outer packaging, or the instructions for use (this may be via over-labelling);
- have a unique device identifier (UDI) on parts and labels in compliance with the (updated) requirements in the new Medical Devices Regulations 2002 or the relevant EU device regulations;
- comply with the post-market surveillance (PMS) requirements in the Medical Devices Regulations 2002; and
- be registered with the MHRA.

The proposed review process is in Table 2. This would require a review by an approved body, but is more streamlined than the UKCA conformity assessment process due to reliance on assessments that have already been performed in the EU.

International reliance route for CE marked devices	**Eligible devices**	**Approved body review**
Route only to be used when the device classification in GB is **higher** than that in the EU	Devices from the EU (using MDR or IVDR): - Class Is/m, IIa, IIb, III MDs - Class B, C, D IVD devices	(a) Confirm market access in the EU (b) Confirm device classification (c) Confirm GB requirements (d) Review PMS plan

		(e) Review PMS data from last 5 years where available

Table 2. The proposed review process for devices undergoing the international reliance route.

The proposed framework would provide a **certificate of international reliance** that can then be used to register with the MHRA and gain access to the GB market but would not provide a UKCA marking or UKCA certification. The validity of the certificate of international reliance for these devices would be in accordance with the EU MDR or EU IVDR certification. Please note that this means that self-declared CE marked Class I devices which would be classified as Class IIa in GB would not be eligible for this route, and would instead need to undergo UKCA conformity assessment. Similarly, self-declared Class A IVD devices which would be classified higher in GB would not be eligible for this route and would also need to undergo UKCA conformity assessment.

Following registration of the device, the MHRA may suspend or restrict market access where it suspects that any of the requirements for market access are not met or if it suspects the device is unsafe.

The manufacturer must keep the information provided during the review process for the longer of –

(a) the lifetime of the device;
(b) 15 years in the case of an implantable device, or 10 years in the case of any other device.

If a substantial change is made to the device, the manufacturer must submit a new application for international reliance.

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, may apply to certain devices. It would be the responsibility of the manufacturer to ensure they meet the appropriate requirements for other applicable legislation.

Annex C: Legal basis and the assessment of the matters set out in section 15 of the Medicines and Medical Devices Act 2021

The Medicines and Medical Devices Act 2021 ('the Act') received Royal Assent on 11 February 2021. We propose to make the legislative changes under consultation in this document, under Part 4 of the Act, which provides powers to make regulations about medical devices.

Section 45 of the Act sets out that, before making regulations, the 'relevant authority' (in this case, the MHRA) must carry out a public consultation. This consultation is conducted in line with the consultation requirements in section 15 of the Act. Section 15 of the Act states that in making regulations the overarching objective must be safeguarding public health and requires when considering whether regulations contribute to this objective, the Secretary of State must have regard to:

1. the **safety** of medical devices;
2. the **availability** of medical devices;
3. the likelihood of the United Kingdom being seen as a **favourable place** in which to:
    a. carry out research relating to medical devices,
    b. develop medical devices, or
    c. manufacture or supply medical devices.

The proposals we have assessed against these criteria are as follows:

1. Extend the current transitional arrangements for devices that comply with the EU Medical Device Directive to align with the transitional timelines in the EU.

2. Indefinitely recognising devices that comply with the EU Medical Device Regulation (EU MDR) and EU In Vitro Diagnostic Medical Devices Regulation (EU IVDR), either for:
a) all devices, or
b) devices that are the same risk class in GB, or lower.

3. Introduce an international reliance route for devices that comply with the EU Medical Device Regulation and EU In Vitro Diagnostic Medical Device Regulation where the risk classification is higher under MDR 2002.

1. Extend the current transitional arrangements for devices that comply with the EU Medical Device Directive to align with the transitional timelines in the EU

The purpose of the proposed policy is to prevent medical device shortages between 31 July 2028 and 31 December 2028 by aligning our timelines for accepting MDD devices with the EU's updated timelines for manufacturers to transition from MDD to EU MDR.

Safety: Devices approved under MDD have been subject to rigorous and independent assessment in the EU (excluding Class I). This policy will help to ensure continuity of supply in medical devices still transitioning from MDD to EU MDR between 31 July and 31 December 2028, which will bring safety benefits to patients who rely on those devices.

Availability: This policy will help to ensure continuity of supply in medical devices still transitioning from MDD to EU MDR between 31 July and 31 December 2028.

Favourable Place: This policy will allow manufacturers to place devices approved under MDD on the GB market until 31 December 2028, minimising complexity and additional regulatory cost. This makes the GB market more favourable for manufacturers of these devices.

2. Indefinitely recognise devices that comply with the EU Medical Device Regulation and EU In Vitro Diagnostic Medical Device Regulation, either for all devices or devices that are the same risk class in GB, or lower.

The purpose of the proposed policy is to enable indefinite market access for CE marked medical devices on the GB market. The impact on safety, availability and favourability may vary depending on whether all devices are recognised, or just devices that are the same risk class in GB, or lower.

Safety: Devices approved under EU MDR and EU IVDR have been subject to rigorous and independent assessment in the EU (excluding Class I), and these regulations meet the recommendations in the Independent Medicines and Medical Devices Safety Review (IMMDSR), which is supportive of device safety. However, the MHRA currently do not have access to information that notified bodies hold on CE marked devices that are then placed on the market in GB, such as surveillance audits, supplier monitoring, and technical file review outputs. This means that the MHRA may take more time to process investigations for CE marked devices in GB, meaning that recalls or corrections may happen slower in the case of non-compliant devices. The MHRA engages with the EU through the Windsor Framework, the Trade and Cooperation Agreement and international forums such as IMDRF to share regulatory updates and information in the interest of patient safety and harmonisation.

Device safety may be improved if only devices that are the same risk class in GB, or lower, were recognised, rather than all devices. This is because devices that are a higher risk class in GB would be subject to the appropriate GB PMS requirements.

Availability: The proposed policy would enable swift market access to most CE marked medical devices and allow patients to benefit from innovative products that have been deemed safe and effective in the EU. It would also help prevent supply disruption for these devices.

Favourable Place: The proposed policy would allow manufacturer resource to be focused on more innovative products for the benefit of patient health. It could also reduce the regulatory burden and costs for developers by minimising potentially duplicative approval processes in the EU and GB.

3. Introduce an international reliance route for devices that comply with the EU Medical Device Regulation and EU In Vitro Diagnostic Medical Device Regulation where the risk classification is higher under MDR 2002.

The purpose of this policy is to ensure that CE marked devices that would be classified higher under MDR 2002 are subject to the higher GB PMS requirements, while still allowing for swift access to these devices.

Safety: The proposed policy would support device safety by ensuring that CE marked devices in GB are subject to the more comprehensive GB PMS requirements if they would be classed higher under MDR 2002, though it should be noted that the conformity assessment will have been undertaken based on the classification in the EU.

Availability: The international reliance route is streamlined compared to the full UKCA conformity assessment process. Though this route has more review steps in comparison to recognition, the number of devices that this route is likely to be open to is small. We also believe that this additional requirement is proportional to ensure patient and public safety and consistency in the requirements that are applied to devices placed on the GB market.

Favourable Place: As mentioned above, the international reliance route is streamlined compared to UKCA conformity assessment. This proposal would also ensure consistency between the PMS requirements applied to devices on the GB market. If we do not do this, then manufacturers of UKCA marked devices may be disadvantaged relative to similar CE marked devices due to the more comprehensive PMS requirements being placed on them.