Medicines & Healthcare products Regulatory Agency

Medical Devices Regulations: Routes to market and *in vitro* diagnostic devices

Consultation

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Ministerial foreword

This government was elected on a manifesto to fix the broken healthcare system, deliver economic growth and usher in a decade of national renewal. The UK has a world-class life sciences and MedTech ecosystem that – with the right regulation – can make an immeasurable difference to patients' experience of the NHS and boost the nation's economy.

There are some excellent examples of groundbreaking medical devices being used to treat patients quickly and effectively in the NHS, but their potential can only be realised if those devices are safe to use. As we work to expand access to new technology it is critical that we have confidence in its safety and effectiveness for patients. We want to create the right regulatory environment to arm the entire health service with safe and effective state-of-the-art equipment and new technology, to bring our analogue NHS into the digital age.

One of this government's long-term missions is to shorten the amount of time people spend in poor health and put the health and social care system on a sustainable footing. We must improve timely access to high-quality healthcare, and we know that access to the right medical devices can decrease trips to hospital and, where necessary, speed up critical treatment. This will make a huge difference to patients and their families, as well as alleviating existing pressures on the NHS.

New technology can help to treat patients more effectively, diagnose illnesses sooner or prevent them altogether, improving outcomes for everybody. For example, at the end of May, there were over 1.6 million people waiting for key diagnostic tests. We must diagnose patients earlier, ensure that they have access to the medical devices they need, and provide peace of mind that those devices are safe and effective. We will work to support innovators, reduce unnecessary bureaucracy and build a health service fit for the future.

We also know that a healthier population enables larger, healthier, more motivated workforces and greater productivity. The health of the nation and the health of the economy are inextricably linked. There are now 2.8 million people inactive due to long-term sickness;[1] improving health and boosting the labour market back to pre-pandemic levels will deliver significant economic growth.

The measures in this consultation are a small but important part of a wider set of reforms to the regulatory framework for medical devices and, furthermore, this government's efforts to eradicate health inequalities, get the NHS back on its feet and kickstart growth across the country. In due course, we will be consulting on further enhancements to the regulatory

[1] UK long term sickness figures 2024 | Statista

framework that will drive forward our health and economic growth agendas. We welcome your views.

Baroness Merron

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

Executive summary

This consultation applies to medical devices in Great Britain. For guidance on the regulation of devices in Northern Ireland, see Regulation of devices in Northern Ireland. We are seeking views from stakeholders on four areas:

1. International reliance

Medical devices and *in vitro* diagnostic devices (IVD devices) can use the UKCA (UK Conformity Assessed) process to access the Great Britain market either by self-certification for low-risk devices, or by conformity assessment and certification by an approved body. Approved bodies are organisations that have been designated by the MHRA to assess medical devices.

In the future regulatory framework, the UKCA process would be complemented by an international reliance scheme to enable swifter market access for certain devices that have already been approved in a comparable regulator country. We are seeking views on the proposed scheme.

2. UKCA marking

Medical devices, or their sterile pack, currently need to have a UKCA marking to be placed on the Great Britain market. We are introducing new requirements to improve device traceability. With these updates in mind, we are seeking views on removing the current marking requirements for devices which undergo the UKCA process.

3. *In vitro* diagnostic devices

IVD devices will be classified in four risk classes based on the patient and public health risk they pose. Each class has different requirements for an IVD device to gain market access, according to its risk level. We are seeking views on the regulatory requirements to gain market access for IVD devices.

4. Assimilated EU law

The final aim of the consultation is to seek views on a proposal to remove the revocation date of four pieces of assimilated law so that they remain part of the statutory framework for medical devices in Great Britain until the transition to an updated medical devices regime. This proposal – alongside more specific transitional provisions – would ensure a smooth transition to a future regulatory framework, which aims to protect patient safety, improve access to innovative medical devices, and support innovation.

There is a statutory requirement to consult publicly before making any regulations under the Medicines and Medical Devices Act 2021. Running discrete consultations allows for the resulting legislation to be more focused and timely. In future, the government intends to consult further on specific legislative measures, such as the expansion of digital labelling and a solution to health institution exemptions that is fit for today's NHS, where care is increasingly delivered in the community.

Introduction

The Medicines and Healthcare products Regulatory Agency (MHRA) is the UK government agency responsible for ensuring that medical devices are safe and effective for use by patients.

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.

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;
- close alignment with international best practice; and
- risk proportionate regulation of medical devices.

The MHRA is inviting members of the public – including patients, medical device researchers, developers, manufacturers and suppliers, 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.

Patient safety

The proposals in this consultation document are just one element of the government's focus on patient safety.

Since the current regulatory framework was introduced, medical technology has advanced significantly, for instance the growth in the use of advanced diagnostics and digital health products involving software and AI, dramatically transforming the quality of care for patients.

Following the Independent Medicines and Medical Devices Safety Review published in July 2020, health systems and the MHRA have taken big steps forward to improve patient involvement and system responsiveness. In the MHRA this work has been under three broad themes: patient and public engagement and involvement; responsive, transparent and timely safety reporting; and improving evidence for patient safety. Actions taken include the creation of a publicly accessible registration system for medical devices, a new SafetyConnect vigilance service in place to report, detect and respond to safety signals more quickly and comprehensively, as well as improving the responsiveness and awareness of our Yellow Card reporting system. The MHRA works in partnership with the NHS Medication Safety Officer and Medical Device Safety Officer networks in the NHS,

and their equivalents in the Devolved Governments, to improve both the handling and communication of safety incidents, as well as meeting regularly with the Patient Safety Commissioner. There is now a need to build on those steps by updating our legal framework.

Background on the regulation of medical devices

Medical devices and IVD devices on the UK market are regulated under the Medical Devices Regulations 2002 (as amended). Those Regulations transpose three EU directives (the Medical Devices Directive (93/42/EEC), Active Implantable Medical Devices Directive (90/385/EEC) and *in vitro* Diagnostic Medical Devices Directive (98/79/EC)) into national law. The MHRA recognises that parts of this regime are out of step with other major international regulatory frameworks and is committed to improving the standards and scrutiny of medical devices that reach patients and members of the public.

In 2021, the previous Government consulted on changes to the Medical Devices Regulations 2002, to improve how medical devices and IVD devices are regulated in the UK. Now, armed with even more information and experience, we intend to take forward the key findings from that consultation to address the most serious patient safety concerns and improve access to much-needed medical devices. These include the need for greater transparency and traceability of the devices given to patients, updated classification of devices, and new requirements for software products, as well as the measures on IVD devices and international reliance set out in this consultation. We have learned important lessons from the implementation of new regulations in the EU, as well as the global approach to international reliance, which have informed our proposals.

On 21 October, we laid The Medical Devices (Post-market Surveillance Requirements) (Amendment) (Great Britain) Regulations 2024 in Parliament, to improve patient safety by mandating the collection and evaluation of data on device safety and performance.

The next step is to implement the proposals from the 2022 response to the consultation that are essential to protecting patient safety, including those that were recommended in the Independent Medicines and Medical Devices Safety Review. Those legislative proposals focus on the measures that must be taken *before* a device can be put on the market. Since 2022, the scope of the legislation we propose to lay has narrowed due to lessons learned from stakeholder engagement and regulatory approaches in other jurisdictions.

We intend to update the regulatory framework by laying secondary legislation concerning:

- classification of general medical devices and IVD devices;
- implantable devices;
- software as a medical device;
- essential requirements;

- unique device identification;
- claims about medical devices;
- common specifications and coronavirus test device approvals; and
- international reliance.

We are undertaking this subsequent consultation to build on the information that we gathered in 2021 and have since continued to evaluate. The responses collected during this more focused consultation will shape parts of this new secondary legislation.

To ensure dual access to both the UK Internal Market and EU Single Market, Northern Ireland applies the EU Medical Device Regulation and EU In Vitro Device Regulation as part of the Windsor Framework. These proposed policy changes will therefore not apply to devices in Northern Ireland. During the development of new regulations, the Government will carefully consider the interaction with arrangements that apply in Northern Ireland.

International Reliance

What is this consultation about?

Currently, medical devices need to have a UKCA (UK Conformity Assessed) marking or a CE marking from the European Union (EU) to be placed on the Great Britain (GB) market. The arrangement for CE marked devices is time limited until 30 June 2030, at the latest, to support the transition following EU exit.

Once the regulatory framework has been amended, the UKCA process would be complemented by an international reliance scheme to enable swifter market access for certain devices that have already been approved as safe and effective in a comparable regulator country. We are seeking views on the proposed framework.

Background

In 2021, the MHRA held a consultation that included introducing alternative routes to market. Views were sought on the following proposals:

- whether the MHRA should introduce an alternative route to market which utilises Medical Device Single Audit Program (MDSAP) certificates. Of 211 responses 86% supported the proposal.
- whether the MHRA should introduce an alternative route to market which utilises approvals from other countries. Of 210 responses 84% supported the proposal.

After careful consideration of responses, the MHRA is proposing to introduce a new framework that would allow certain medical devices that have been approved by other countries to be placed on the GB market without needing a UKCA marking or UKCA certification.

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.

The MHRA has identified four countries or jurisdictions that have comparable regulatory systems to the UK: Australia, Canada, the EU and the USA. The criteria for determining which systems are ‘comparable’ includes similarity of population, market size and pre-market regulatory requirements. 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.

Manufacturers utilising the new International Reliance route would be required to register their products with the MHRA and through its new post-market surveillance regulations, the MHRA would continue to monitor the performance and safety of all medical devices on the GB market, including those that have come via the International Reliance route. These regulations ensure that devices entering the market take a consistent approach to PMS and provide the MHRA with good quality data to identify and respond to issues more quickly and take appropriate actions if needed.

Manufacturers of medical devices would still have the option to use the UKCA process to place devices on the GB market. The international reliance framework offers an alternative for products that have already been through an equivalent or near equivalent process in a comparable regulator country. International reliance as proposed in this consultation would be a unilateral agreement, although a longer-term ambition would be to seek mutual arrangements with certain other regulators. The international reliance framework would not affect the arrangements for qualifying Northern Ireland goods, which will continue to have unfettered access to the Great Britain market, and may continue to be placed on the GB market on the basis of a valid CE marking.

In May 2024, the MHRA issued a policy of statement intent for international recognition of medical devices. Since then, we have been testing the proposed framework with a range of devices across all classifications and types in collaboration with industry, designated approved bodies, and applicant approved bodies going through the designation process, to establish the process.

The proposed framework has been updated based on these activities, which is described in the following section. The name of the scheme has changed from 'international recognition' to 'international reliance' to align with the definitions from the World Health Organization.

'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 MHRA continues to review the list of comparable regulator countries and is in active discussions with the Pharmaceuticals and Medical Devices Agency to explore the reliance of medical device approvals from Japan.

How would the proposed framework work?

International recognition

CE marked devices from the European Union (EU) may continue to be placed on the GB market until 30 June 2028 or 30 June 2030, depending on the device, to support the transition following EU exit. This is international recognition. Following the ending of these transition arrangements, the routes to market for CE marked products set out below under 'International reliance' will apply.

International reliance

We propose to introduce a new route to market using international reliance for certain devices depending on the type and classification of the device, and prior approval. We propose that only certain requirements in the UK Medical Devices Regulations apply to certain devices where they already have marketing authorisation in Australia, Canada, USA or EU (with a delayed implementation following transitional arrangements) and a certified Quality Management System (QMS).

To be eligible for any of the access routes, the medical devices must:

- fall within the scope of the UK Medical Devices Regulations;
- be classified in accordance with UK Medical Devices Regulations. The classification of general medical devices in UK law is based on the level of risk they pose to the user, ranging from Class I (lowest risk) to Class III (highest risk). Later in this consultation, we explain how we intend to implement the commitment to introduce a new classification system for IVD devices from Class A (lowest risk) to Class D (highest risk). IVD devices are devices that are used to analyse samples from the human body, such as blood or urine, to provide information on health conditions or diseases. This new IVD classification system is used in the proposed framework;
- have English language labelling and packaging;
- be supplied with an implant card and leaflet in compliance with the (updated) requirements in the new UK Medical Devices Regulations, where applicable;
- 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 (for example, for substances which are carcinogenic, mutagenic or toxic to reproduction (CMR), of category 1A or 1B, or could result in sensitisation or an allergic reaction);
- 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, and MHRA will also investigate the ability for digital labelling or digital label solutions in a future consultation);
- have a physical unique device identifier (UDI) on parts and labels in compliance with the (updated) requirements in the new UK Medical Devices Regulations or the CRC;
- comply with the new post-market surveillance (PMS) requirements in the UK Medical Devices Regulations 2002, which are expected to come into force in 2025; and
- register with the MHRA.

The four proposed access routes are summarised in the table below.

The proposed review process is streamlined in comparison to the UKCA conformity assessment process due to reliance on assessments that have already been performed in the CRC. Some routes require a review by approved bodies. Approved bodies are organisations that have been designated by the MHRA to assess medical devices.

Route	Eligible Devices	Approved Body Review

Route 1	Low risk devices that comply with devices legislation in Australia, Canada, EU and the USA: - Class I medical devices (MDs), other than Class Is/m (Is: Class I sterile device; Im: Class I device with a measuring function) - Class A IVD devices which are non-sterile	No approved body review is required. A self-declaration for an appropriate Quality Management System (QMS) must be provided to the MHRA during registration
Route 2	Non-active devices from the EU (using MDR or IVDR): - Class Is/m, IIa, IIb, III MDs - sterile Class A IVD devices - Class B, C, D IVD devices	The approved body must: (a) Confirm CRC marketing authorisation (b) Confirm device's GB classification (c) Confirm GB requirements (d) Review PMS plan (e) Review PMS data from last 5 years where available
Route 3	Non-active devices that comply with device legislation in Australia, Canada (using Class III or Class IV licence) and the USA (using De Novo, PMA or 510(k))*: - Class Is/m, IIa, IIb, III** MDs - sterile Class A IVD devices - Class B, C IVD devices **Excluding devices listed in Route 4* ***For devices from Canada, only devices with a Class IV licence in Canada would be able to enter this route as a Class III device in GB*	The approved body must: (a) Perform (a) – (e) in Route 2 (b) Confirm that the implant card and patient leaflet, if applicable, meets the (updated) UK MDR requirements (c) Confirm that the instructions for use provided with reusable devices, if applicable, contains information on the appropriate processes to allow reuse, including cleaning, disinfection, packaging and, where appropriate, the method of sterilisation, and any restriction on the number of reuses
Route 4	- Class IIa, IIb (non-implantable) and IIb non-resorbable sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips or connectors that comply with 510(k) legislation in the USA - medical devices that incorporate an ancillary medicinal substance from Australia, Canada (using Class III or Class IV licence*) or the USA - Class D IVD devices that comply with devices legislation in Australia, Canada and the USA - Active devices that comply with devices legislation in Australia, Canada (using Class III or Class IV licence*), EU (using MDR or IVDR), and the USA (using De Novo, PMA or 510(k)) **For devices from Canada, only devices with a Class IV licence in Canada would be able to enter this route as a Class III device in GB*	The approved body must: (a) Perform (a) – (c) in Route 3, and (b) Confirm that the rationale for equivalence to a "reference device" for 510(k) devices meets the (new) UK MDR requirements (see Annex C) (c) Obtain an opinion on the quality and safety of any ancillary medicinal substance incorporated into the device from the Secretary of State (d) Confirm Class D IVD devices meet batch test release requirements (e) Confirm active devices are compatible with electrical requirements in GB (f) For software as a medical device, review information that demonstrates there are no differences between the CRC and GB that adversely impact on the safety or efficacy of the device and the appropriateness of any pre-determined change control plans.

The following devices would not be eligible for any of the access routes:

- software as a medical device that has gained access to the USA market via the FDA 510(k) clearance process
- devices that comply with 510(k) legislation in the USA that are classified in GB as Class IIb implantable (excluding the devices listed in Route 4) and Class III
- devices granted market access in CRC via reliance routes
- devices that contain non-viable cells and tissues of human origin

The following devices would only be eligible for Route 2:

- medical devices that utilise animal tissues and their derivatives
- medicinal products that include a medical device in the secondary packaging of the medicinal product (i.e. co-packaged)
- companion diagnostics

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.

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.

For devices from Australia, the validity for the Certificate of International Reliance would be in accordance with the TGA conformity assessment certification.

Subsequent to the international recognition of EU medical devices during the transitional arrangements period, for devices from the EU, the validity of the Certificate of International Reliance would be in accordance with the EU MDR or IVDR certification.

For devices from Canada or the USA, the validity for the Certificate of International Reliance would be in accordance with the QMS (for example, the Medical Device Single Audit Program (MDSAP) or accredited ISO 13485) certification.

Following registration of the device, the MHRA may suspend or cancel the Certificate of International Reliance where we believe that any of the requirements for market access are not met.

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 significant change is made to the device, the manufacturer must submit a new application for international reliance, unless the device is software as a medical device and has a predetermined change control plan.

The proposed framework would have a transition period of 12 months.

In May 2024, the MHRA issued a statement of policy intent which included specific requirements for Artificial Intelligence as a Medical Device (AIaMD), which is a subset of software as a medical device.

However, the government does not intend to define AIaMD or introduce any AIaMD-specific requirements in legislation at this time. Therefore, the proposed framework does not include specific requirements for these devices.

These devices have potential to help our healthcare system with diagnosis and screening, prognosis and supporting treatment. AIaMD also pose specific safety challenges such as performance degradation and the potential for unwanted bias being built in during development, particularly against under-represented groups such as ethnic minorities. Therefore, we propose that all software as a medical device would initially only be eligible for Route 4 in the proposed framework.

We welcome your interest and participation in this consultation. 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.

Questions

C1. Do you agree with all elements of the MHRA's proposed international reliance routes?

Yes (if yes, proceed to Question C6)

No (if no, proceed to Question C2)

No opinion

C2. Would you like to see the proposed Route 1 introduced?

Yes (include short explanatory text if appropriate)

No (include short explanatory text if appropriate)

No opinion

C3. Would you like to see the proposed Route 2 introduced?

Yes (include short explanatory text if appropriate)

No (include short explanatory text if appropriate)

No opinion

C4. Would you like to see the proposed Route 3 introduced?

Yes (include short explanatory text if appropriate)

No (include short explanatory text if appropriate)

No opinion

C5. Would you like to see the proposed Route 4 introduced?

Yes (include short explanatory text if appropriate)

No (include short explanatory text if appropriate)

No opinion

C6. Certain medical devices approved via 510(k) are excluded in the framework above:

- software as a medical device
- implantable Class IIb devices other than non-resorbable sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips or connectors
- Class III medical devices

Would you like to see these devices added into the scope of Route 4 if their rationale for equivalence to a "reference device" meets the (new) UK MDR requirements for entire equivalence on a biological, technical and clinical basis? *Please note that these requirements are summarised in Annex C to support this decision.*

Yes (include short explanatory text if appropriate)

No (include short explanatory text if appropriate)

No opinion

UKCA marking

What is this consultation about?

We are seeking views on removing the current requirements for devices which undergo the UK conformity assessment process to bear a 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.

This marking is not specific to medical devices and you may have seen this on other goods around your house, such as electronics and toys.

On a medical device, this indicates that the device meets the requirements of the UK Medical Devices Regulations 2002.

In 2021, the MHRA invited views on whether the UK medical devices regulations should define 'Unique Device Identification' (UDI) to improve the traceability of medical devices. 274 respondents were received, of which 91% were in favour.

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.

It remains the intention to require manufacturers to assign UDIs to medical devices before they are placed on the GB market and to register these UDI numbers with the MHRA when placing a device on the market in GB.

This also supports the NHS initiative Scan4Safety, which is the implementation of unique barcodes for patients, medical equipment, and products used in healthcare settings. Each barcode is associated with detailed information, ensuring accurate identification and tracking.

The Proposal

The requirement for UKCA certified products to carry the UKCA mark potentially creates a barrier to market for manufacturers. Manufactures are required to maintain a separate line of UKCA-marked products for the relatively small GB market.

As the new UDI requirements would improve the traceability of medical devices, the MHRA propose to remove the requirement for UKCA marking for devices which have been through the UK conformity assessment process. This would mean that a UKCA mark

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.

Question

C7. Do you support the proposal to remove the UKCA marking requirement for devices which undergo the UK conformity assessment process?

Yes (include short explanatory text if appropriate)

No (include short explanatory text if appropriate)

No opinion

C8. Do you support the proposal to remove the UKCA marking requirement for medical device labelling (e.g. packaging and instructions for use) for devices which undergo the UK conformity assessment process?

Yes (include short explanatory text if appropriate)

No (include short explanatory text if appropriate)

No opinion

In Vitro Diagnostic Devices

What is this consultation about?

We are seeking views on the regulatory requirements for IVD devices to gain market access using the UKCA process. IVD devices are classified into four risk classes based on the patient and public health risk posed by the IVD device. Each class has different requirements for an IVD device to gain market access; as the risk level increases, the regulatory requirements become more stringent and more oversight is required. Therefore, to ensure that our new classification system for IVD devices is risk proportionate, we are assessing the applicable requirements. Our aim is to ensure that we continue to protect patient safety while not creating a disproportionate regulatory burden for low-risk devices.

Please refer to Annex D for background information about IVD devices.

How are IVD devices classified?

In November 2021, the MHRA held a consultation that included changing the classification system for IVD devices. Views were sought on the following proposals:

- Whether the classification rules for IVD devices should be amended to align to the EU IVDR. Of 138 responses 80% supported the proposal.

- Whether the classification rules for IVD devices should be amended to align to the principles developed by the International Medical Device Regulators Forum (IMDRF). Of 136 respondents 56% supported the proposal.

- Whether the current IVD regulatory requirements for each class of IVD devices are proportionate to their risk. Of 135 responses: 21% felt they are proportionate and 57% felt that they are not proportionate.

- Whether the current approach to classification sufficiently covers the digital/software aspect of the IVD device, 136 respondents provided views, of which 11% felt the current approach is sufficient and 51% felt that the current approach is not sufficient.

Respondents were also invited to provide reasoning for their responses, which can be summarised as follows:

- Many respondents indicated that alignment with the EU would provide economic and operational benefits to manufacturers.

- Some respondents noted that global harmonisation (both in the context of the EU and the IMDRF) would provide wider choice to patients and would make the UK a more attractive destination to manufacturers.

- Many respondents felt that mirroring a risk-based approach to classification would be favourable.

To address the issues mentioned and ensure that high risk IVD devices are classified appropriately according to risk, the MHRA will amend the IVD classification system, introducing a series of rules which align GB more closely with the structure used by the IMDRF and EU. This is to support global harmonisation efforts and assist in providing a risk-based approach to classification of IVD devices. The new classification system will consist of four classes: A, B, C, and D, with Class A being the lowest risk and Class D being the highest risk (see Table 1).

Table 1. New IVD Classification system

New Classification System	Risk level
Class A	Low Individual Risk and Low Public Health Risk
Class B (incl. self-test devices not in a critical situation*)	Moderate Individual Risk and/or Low Public health Risk
Class C (incl. self-test)	High Individual Risk and/or Moderate Public Health Risk
Class D	High Individual Risk and High Public Health Risk

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

Currently, to gain access to the GB market, depending on the classification of the IVD device, manufacturers must complete either a self-declaration or conformity assessment undertaken by a UK approved body, against a set of essential requirements. The essential requirements will be updated to align with the general safety and performance requirements in the EU as set out in Reg (EU) 2017/746.

Proposal: Conformity assessment procedure

The MHRA has explored several options for the associated conformity assessments for the new IVD classification system, with the policy aim of ensuring that we have the appropriate patient safety controls in place that are risk proportionate. We propose the following conformity assessment procedure for each IVD device classification, with the level of regulatory scrutiny increasing with the level of risk (further detail can be found in table 4):

- Class A IVD devices: UKCA self-declaration of conformity
- Class B IVD devices: UKCA self-declaration of conformity + Quality Management System (QMS) certification
- 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

Table 4. Proposed IVD routes to market for each class

Classification System	Risk level	Market Access	Specific Requirements
Class A*	Low Individual Risk and Low Public Health Risk	UKCA self-declaration of conformity	• Self-declaration against the relevant Essential Requirements • Ensure the device fulfils the applicable obligations described in IVDD Annex III
Class B* (incl. self-test devices not in a critical situation)	Moderate Individual Risk and/or Low Public health Risk	UKCA self-declaration of conformity + QMS certification	• Self-declaration against the relevant Essential Requirements • Ensure the device fulfils the applicable obligations described in IVDD Annex III • QMS certification to ISO13485, issued by a certification body accredited by UKAS
Class C (incl. self-test)	High Individual Risk and/or Moderate Public Health Risk	UKCA conformity assessment by an Approved Body	• IVDD Annex IV Audit of QMS or MDSAP • Audit technical documentation (sample only)
Class D	High Individual Risk and High Public Health Risk	UKCA conformity assessment by an Approved Body	• Design dossier review • IVDD Annex IV Audit of QMS or MDSAP • Batch released by approved body • Common Specification requirements

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

The new IVD classification system closely aligns GB with the EU, however the regulatory requirements to gain market access would be more risk proportionate for GB, in particular for Class B IVD devices which would undergo a CE conformity assessment by a notified body in the EU.

The driver for the proposed approach is the public health risk level of Class B IVD devices. Class B IVD devices have moderate individual risk and/or low public health risk. In line with our aim for risk proportionate patient safety controls in place, we propose that a UKCA self-declaration of conformity and QMS certification to ISO 13485 are suitable pre-market controls to ensure that a Class B IVD device is safe for patient use.

A Quality Management System (QMS) is a system intended to ensure that the manufacturer has the appropriate infrastructure and procedures in place to consistently manufacture medical devices which meet the requirements of the Medical Devices Regulations 2002 (as amended). There are various standards and frameworks that can help an organisation to establish and maintain a QMS, such as ISO 13485:2016. ISO 13485 is the most widely recognised and adopted international standard for quality management for medical devices, which provides the principles, requirements, and guidelines for a QMS.

It is proposed that the conformity assessment processes for Class A, C, and D would stay closely aligned with the EU. We recently held a consultation in May 2024 on the common specification requirements for certain high risk (Class D) IVD devices. Following the consultation, we intend to proceed with the proposal to introduce common specification requirements as part of the Class D conformity assessment procedure.

The conformity assessment processes for Class A, B, C, and D IVD devices will apply to IVD devices that are also Software, due to our intention to include Software in the definition of an IVD as proposed in the 2021 consultation.

To ensure dual access to both the UK Internal Market and EU Single Market, Northern Ireland applies the EU in vitro Diagnostic Medical Devices Regulation (2017/746) (EU IVDR). The proposed approach would therefore mean this class of IVD devices would need to undergo a CE conformity assessment by a notified body in order to gain market access in NI.

Questions

C9. Do you support the proposed conformity assessment processes for IVD devices (including Software IVDs) in Great Britain?

Yes (include short explanatory text if appropriate)

No (include short explanatory text if appropriate)

No opinion

C10. Do you think that UKCA declaration of conformity and QMS certification are adequate pre-market controls for Class B IVD devices?

Yes (include short explanatory text if appropriate)

No (include short explanatory text if appropriate)

No opinion

C11. Do you support the requirement for ISO13485:2016 standard to be met for Class B IVD devices?

Yes (include short explanatory text if appropriate)

No (include short explanatory text if appropriate)

No opinion

C12. If the proposed approach is implemented, do you think that Class A and B IVD devices should be removed from the scope of international reliance?

Yes (include short explanatory text if appropriate)

No (include short explanatory text if appropriate)

No opinion

Assimilated EU Law

What is this consultation about?

The Medical Devices Regulations 2002 transposed relevant EU Directives into domestic law and is therefore considered to be 'assimilated' EU law. The Regulations contain references to a number of other pieces of assimilated EU law, which also form part of the regulatory framework for GB. Please refer to Annex E for further information about assimilated EU law.

The Government is committed to ensuring that the regulations for medical devices continue to prioritise patient safety and give patients access to the medical devices they need. As mentioned above, the government intends to make a number of updates to the Regulations in order to achieve this aim. Four of the pieces of assimilated law that form part of GB's current regulatory framework are due to be sunsetted – i.e. they are due to expire – on 26 May 2025 (before any new Regulations are in force); please refer to regulations 4H, 4J, 4K and 4L of The Medical Devices Regulations 2002. The purpose of those regulations can be summarised as follows:

- **Commission Decision 2002/364 on the common specifications for *in vitro* diagnostic medical devices** sets out common specifications that certain *in vitro* diagnostic medical devices must meet to demonstrate compliance with essential requirements when they are placed on the market or put into service.
- **Commission Regulation (EU) No 207/2012 on electronic instructions for use of medical devices** establishes the conditions under which the instructions for use of medical devices may be provided in electronic form instead of in paper form and sets out certain requirements concerning instructions for use in electronic form which are provided in addition to complete instructions for use in paper form.
- **Regulation (EU) No 722/2012 concerning particular requirements for medical devices manufactured utilising tissues of animal origin** lays down requirements in relation to the placing on the market and putting into service of medical devices, including active implantable medical devices, manufactured utilising animal tissue which is rendered non-viable or non-viable products derived from animal tissue. The Regulation applies to animal tissues, as well as their derivatives, originating from bovine, ovine and caprine species, deer, elk, mink and cats.
- **Regulation (EU) No 920/2013 on the designation and the supervision of approved bodies** sets out further requirements on the designation of approved bodies and a list of elements to be included in the interpretation of the relevant Directive annexes on minimum criteria to be met for the designation of bodies.

The proposal

As these regulations are still in use, the MHRA proposes to maintain the regulatory status quo by removing the revocation date of these four pieces of assimilated law so that they continue to apply in GB until such time as they are replaced with updated UK law. Allowing these regulations to be sunsetted on 26 May 2025 would cause significant disruption to the regulatory framework and, consequently, negative impacts on patient safety.

Questions

C12. Do you agree with the MHRA's proposal to remove the revocation date of the four specified pieces of assimilated EU law?

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. Business

c. Patient group

d. Professional representative group

e. Professional regulator

f. Research organisation

g. 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 business 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]

[if selected D2E.c] D2F. Does your business produce or supply any of the devices affected by common specification measures?

a. COVID-19 tests

b. Other

c. Don’t know

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).

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;
- your name and name of your organisation;
- 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 (SocialOptic), who is responsible for running and hosting the online survey

No personally identifiable data will be shared.

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

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

“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: 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.

We have assessed the four proposals against each of these factors, outlined below.

1. International Reliance: The purpose of the proposed policy for international reliance is to ensure access to quality-assured medical devices.

Safety: The proposed policy would ensure that devices are subject to rigorous and independent assessment by countries and jurisdictions with comparable regulatory systems to the UK. GB-specific requirements would also be reviewed by approved bodies, including a robust system of post-market surveillance to allow for timely detection and resolution of any safety issues or risks.

Availability: The proposed policy would maintain and enhance the availability of medical devices in GB by reducing manufacturers' duplication of regulatory assessments and streamlining the pre-market application process, supporting GB as a favourable market to place a medical device.

Favourability: The proposed policy would allow regulatory resource, and manufacturer resource, to be focused on more innovative products for the benefit of patient health. It would allow developers to choose the most suitable and efficient route for their device based on the approvals they already have. It could also reduce the regulatory burden and

costs for developers, as they would not have to undergo multiple assessments and audits for different jurisdictions.

2. UKCA marking: The purpose of the proposed policy is to streamline the labelling requirements for medical devices that undergo the UKCA conformity assessment process

Safety: The proposed policy may have a perceived impact on patient safety since there would be no visible UKCA mark on the devices to indicate that the part has been through a conformity assessment which may make it easier for counterfeit goods to enter the market. However, this is addressed by the new UDI requirements which will improve the traceability of medical devices beyond the current processes and will be searchable in a public-facing database, where its conformity assessment process can be verified. Therefore it has been determined that this policy has no impact on patient safety.

Availability: The proposed policy would facilitate the availability of medical devices in GB by reducing the costs associated with design updates and direct part marking related to the UKCA mark, therefore more manufacturers may choose to use the UKCA process.

Favourability: The proposed policy would facilitate the manufacture of medical devices in GB by reducing the resource associated with design updates and direct part marking related to the UKCA mark, therefore more manufacturers may choose to use the UKCA process and develop medical devices in the UK.

3. IVD Classification and routes to market: The purpose of the proposed policy for IVD Classification and routes to market is to ensure that the regulatory requirements for IVD devices are proportionate to the public health risk of the device.

Safety: The proposed policy addresses the safety of IVD device by amending the IVD classification system to align more closely with the structure used by the International Medical Device Regulators Forum (IMDRF), supporting global harmonisation efforts and providing a risk-based approach to classification of IVD devices. The new classification system would include additional rules to better reflect public health risks in the UK, such as higher classification of life-threatening diseases and inclusion of cardiovascular and neurodegenerative diseases in Class C.

Availability: The proposed policy maintains the availability of IVD devices by ensuring that the requirements for IVD devices to gain market access, continue to protect patient safety without creating a greater regulatory burden for low-risk devices, which could risk market disruption, or disproportionate risk classification to public health risk. The MHRA explored options for reforming the routes to market based on the new classification system and the proposed changes to the market access requirements for IVD devices classified as Class B mitigates possible risk of supply disruption.

Favourability: The proposed policy only applies in GB. It will support the likelihood of GB being seen as a favourable place for research, development, or manufacturing of medical devices through the policy objectives to improve patient and public safety, foster innovation, align closely with international best practice, and ensure proportionate regulation of medical devices. The proposed policy approach includes changing the market access requirements for IVD devices to be more risk proportionate, which would make GB a more attractive destination to manufacturers.

4. Assimilated EU law: The purpose of the proposed policy is to avoid unintended interruption to the regulatory framework for medical devices and, consequently, negative impacts on patient safety.

Safety: The proposed policy to maintain the relevant pieces of assimilated tertiary EU law will ensure that there is continuity in the regulatory controls for medical devices on the GB market.

Availability: The proposed policy to maintain the tertiary law mentioned above will not affect the availability of medical devices, since this is the status quo.

Favourability: The proposed policy to maintain the tertiary law mentioned above will not affect the favourability of the UK, since this is the status quo.

Annex C: Equivalence

The future regulations will introduce new requirements regarding equivalence. They are summarised below to help support your decision making for question C6.

In order to demonstrate entire equivalence between the relevant device and the device to which equivalence is claimed, the manufacturer must take into consideration the following characteristics—

(a) technical characteristics, where the relevant device and the device to which equivalence is claimed—

(i) are of similar design;

(ii) are used under similar conditions of use;

(iii) have similar specifications and properties including physicochemical properties such as intensity of energy, tensile strength, viscosity, surface characteristics, wavelength and software;

(iv) where relevant, use similar deployment methods;

(v) have similar principles of operation and critical performance requirements;

(b) biological characteristics where the relevant device and the device to which equivalence is claimed use materials that do not result in new or increased biological risks;

(c) clinical characteristics where the relevant device and the device to which equivalence is claimed —

(i) are used for the same clinical condition or purpose, including similar severity and stage of disease, at the same site in the body, in a similar population, including as regards age, anatomy, ethnicity and physiology;

(ii) have the same category of user;

(iii) have similar relevant critical performance in view of the expected clinical effect for a specific intended purpose.

All three of the technical, biological and clinical characteristics listed above must be similar to the extent that there is no clinically significant difference in the safety and clinical performance of the relevant device, unless the difference has been introduced to improve the safety and clinical performance of the relevant device.

The manufacturer's consideration of the above characteristics must be:

(a) based on proper scientific justification;

(b) based on a risk-based approach, when identifying and assessing the characteristics of a relevant device that may affect performance and safety.

In the case of a relevant device that is software–

(a) the manufacturer must ensure that the intended purpose, diagnostic or therapeutic purpose, data inputs and outputs including model type and training data, where applicable, of the relevant device is the same as the device to which equivalence is claimed; and

(b) software that is only for the purpose of configuration of the relevant device and is not related to the intended purpose of the relevant device does not need to be included in the manufacturer's demonstration of equivalence.

The clinical data used by the manufacturer to demonstrate equivalence must relate to a specific version of the device to which equivalence is claimed.

Where a manufacturer is demonstrating equivalence in respect of a relevant device which is an implantable device falling within Class IIb or falls within Class III, the device to which equivalence is claimed must–

(a) bear a UKCA marking or a CE marking or

(b) have a Certificate of International Reliance

Annex D: Background on IVD Regulation

An IVD device is used to examine samples taken from the human body. Samples can include saliva, blood, tissue, urine. They are used to diagnose and monitor health conditions such as flu infections, glucose levels, and hepatitis. They can also be used as a prevention measure by screening people for possible health conditions such as cancer. Examples of IVD devices include pregnancy tests, genetic tests for prenatal screening, pap smears tests for cervical cancer screening, blood glucose meters for monitoring diabetes, and HIV testing kits.

IVD devices in Great Britain (England, Wales and Scotland) are currently regulated by the Medicines and Medical Devices Act 2021 and the Medical Devices Regulations 2002. Under the terms of the Windsor Framework, Northern Ireland continues to follow EU regulations for IVD devices, the IVDR. Provisions implementing the IVDR in Northern Ireland are set out in the Medical Devices (Northern Ireland Protocol) Regulations 2021.

Under the Medical Devices Regulations 2002, manufacturers of IVD devices must ensure their products meet relevant regulatory requirements before placing them on the market or putting them into service. Depending on the Classification of the device, IVD devices will either be required to undergo conformity assessment or submit a self-declaration. A conformity assessment is undertaken by an UK Approved Body to demonstrate conformity to the relevant regulatory requirements for the IVD device, before gaining market access. This requires manufacturers to demonstrate conformity to the required standards and to also provide information to support their performance claims for their IVD device. In many cases, this information will come from a performance study of the device.

Once a medical device is on the market, the manufacturer must continue to assess the safety and performance of that IVD device. This is known as ‘post-market surveillance’. The manufacturer should also report certain incidents involving the IVD device to the MHRA. This is known as ‘vigilance’. You can read more about existing requirements for placing a IVD device on the Great Britain market in MHRA guidance.

The lifecycle of an IVD device can be found in Figure 1. This consultation does not cover the regulation of the full lifecycle of an IVD device. It covers pre-market approval of IVD

devices (boxes outlined in red in Figure 1).

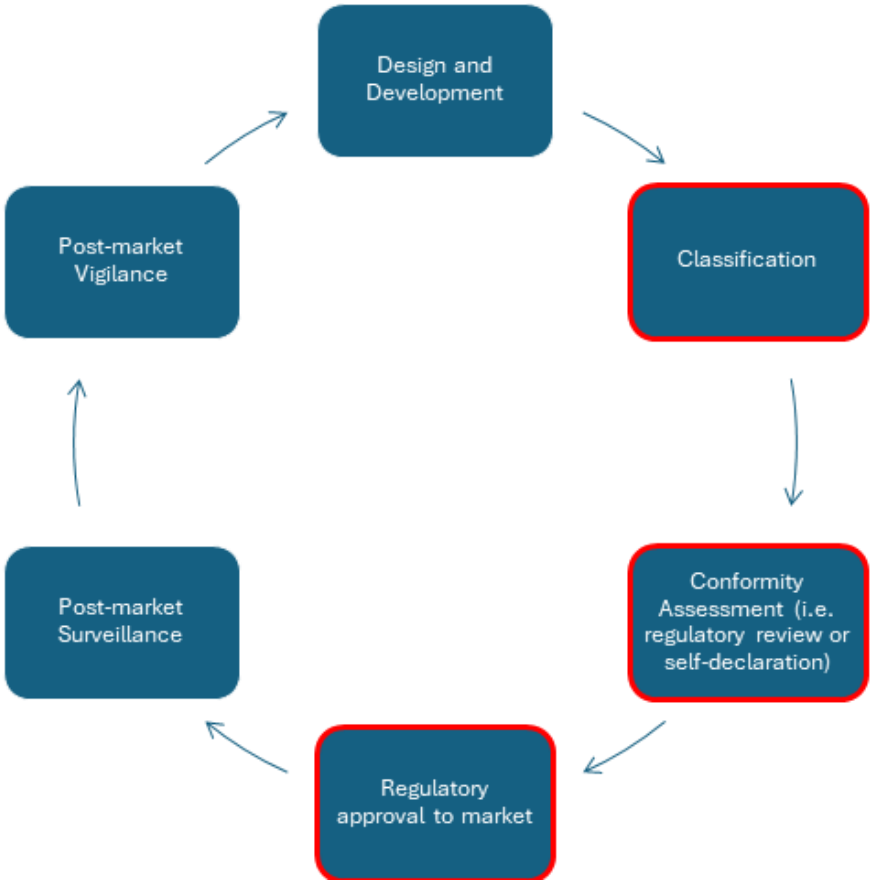

Figure 1. Life Cycle of an In-Vitro Diagnostic Medical Device

IVD Classification

IVD devices are currently classified into four categories (see Table 1). The current classification system does not proportionately regulate IVD devices according to their risk to the individual and public health. It is a disease-based classification system that reflects the diseases that were high risk in the past, but not the higher risk diseases of today and the future.

Table 1. Current IVD classification system (in order of highest to lowest risk classes)

Current IVD Classification	**Examples (not exhaustive)**
List A	HIV, Hepatitis, ABO Blood Grouping
List B	Rubella, PSA, Self-test for Blood Glucose
Self-test	Pregnancy and Cholesterol home tests
General	Tests for hormones, Cardiac Markers, Haematology, and Clinical Chemistry tests

Having considered the views of respondents, from the November 2021 consultation and including issues outlined, we will be amending the Classification system. The new classification system will consist of four classes: A, B, C, and D, with Class A being the lowest risk and Class D being the highest risk (see Table 2). IVD devices will be classified into one of the four classes by applying a set of rules which will closely align with the International Medical Device Regulators Forum (IMDRF) classification rules for IVD devices with some exceptions. The exceptions include additional rules to better reflect the public health risks in the UK, such as higher classification of life-threatening diseases and addition of cardiovascular and neurodegenerative diseases in Class C.

The IMDRF rules are effectively a set of principles, which we should apply in a manner that is most relevant to the UK to classify IVD devices. For example, certain self-tests described as examples in the IMDRF guidance as Class B may instead be classified as a Class C in the UK, given the corresponding level of public health risk in this country.

Table 1. New IVD Classification system

New Classification System	**Risk level**
Class A	Low Individual Risk and Low Public Health Risk
Class B (incl. self-test devices not in a critical situation)	Moderate Individual Risk and/or Low Public health Risk
Class C (incl. self-test)	High Individual Risk and/or Moderate Public Health Risk
Class D	High Individual Risk and High Public Health Risk

Table 3 shows how the new IVD classification reclassifies majority of IVD devices into a higher risk class (i.e. Class B, C or D) demonstrating that majority of IVD devices were not appropriately classified by risk under the old classification system.

Table 2. Mapping current classes to future IMDRF classes

From current IVD classification	*To* new IVD Classification	Examples
List A *(ABO blood grouping, Rhesus system, anti-Kell)*	D	Hepatitis B/C/D, HIV 1&2, HTLV I & II, ABO blood grouping system, Rhesus system, Anti-Kell
List B *(anti-Duffy, anti-Kidd, anti-erythrocytic antibodies, rubella, taxoplasmosis, phenylketonuria, cyctomegalovirus, chlamydia, HLA tissue typing, PSA, trisomy 21,*	D	Anti-Duffy, Anti-Kidd
	C	Determine foeto-maternal blood group incompatibility (Trisonomy 21), or HLA tissue typing (DR/A/B), Cytomegalovirus, PSA & cancer tests, Chlamydia trachomatis, rubella, taxoplasmosis, Blood sugar measurement
	B	Anti-erythrocytic antibodies

measurement of blood sugars)		
Self-test	C	All self-tests where it does determine a critical situation*
	B	Self-tests for non-critical situations eg. Fertility tests
General	D	Variant Creutzfeldt-Jakob disease, Epstein-Barr virus infection, Treponema pallidum, Trypanosoma cruzi, COVID-19 tests
	C	Tests for transfusion/transplantation or cell administration, Genetic/Genomic tests, companion diagnostics, congenital disorders in foetus, Neisseria gonorrhoeae, Neisseria meningitidis or Cryptococcus neoformans, Chlamydia pneumoniae, G6PD, Troponin
	B	Blood gases, H. pylori test, liver function test for AST/ALP, Urinalysis controls and chemistry control and controls without a quantitative or qualitative assigned value
	A	Specimen receptacle, culture media, wash solutions, instruments and analysers

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

Annex E: Background on Assimilated EU Law

What is ‘assimilated EU law’?

‘Retained EU Law’ (or ‘REUL’) was a type of domestic law created by the EU (Withdrawal) Act 2018 and came into effect at the end of the UK’s post-Brexit transition period (which ended on 31 December 2020). The primary objective of REUL was to provide legal continuity and certainty at the end of the transition period.

On 29 June 2023, the Retained EU Law (Revocation and Reform) Bill 2023 received Royal Assent. Under that Act, REUL that had not been revoked by the end of 2023 became ‘assimilated law.’ Unlike REUL, assimilated law is not interpreted in line with EU principles of interpretation; these were removed from domestic law by the REUL Act with effect from 1 January 2024. Further information can be found at GOV.UK.

What does ‘sunsetting’ mean?

A sunset clause sets a time limit on legislation. It sets out that the legislation will expire at a specified point in the future. This has the same effect as repealing or revoking the legislation – it is no longer law, but anything done under it while it was law remains valid. If the Government wishes to extend the legislation beyond that date, it must enact new legislation.