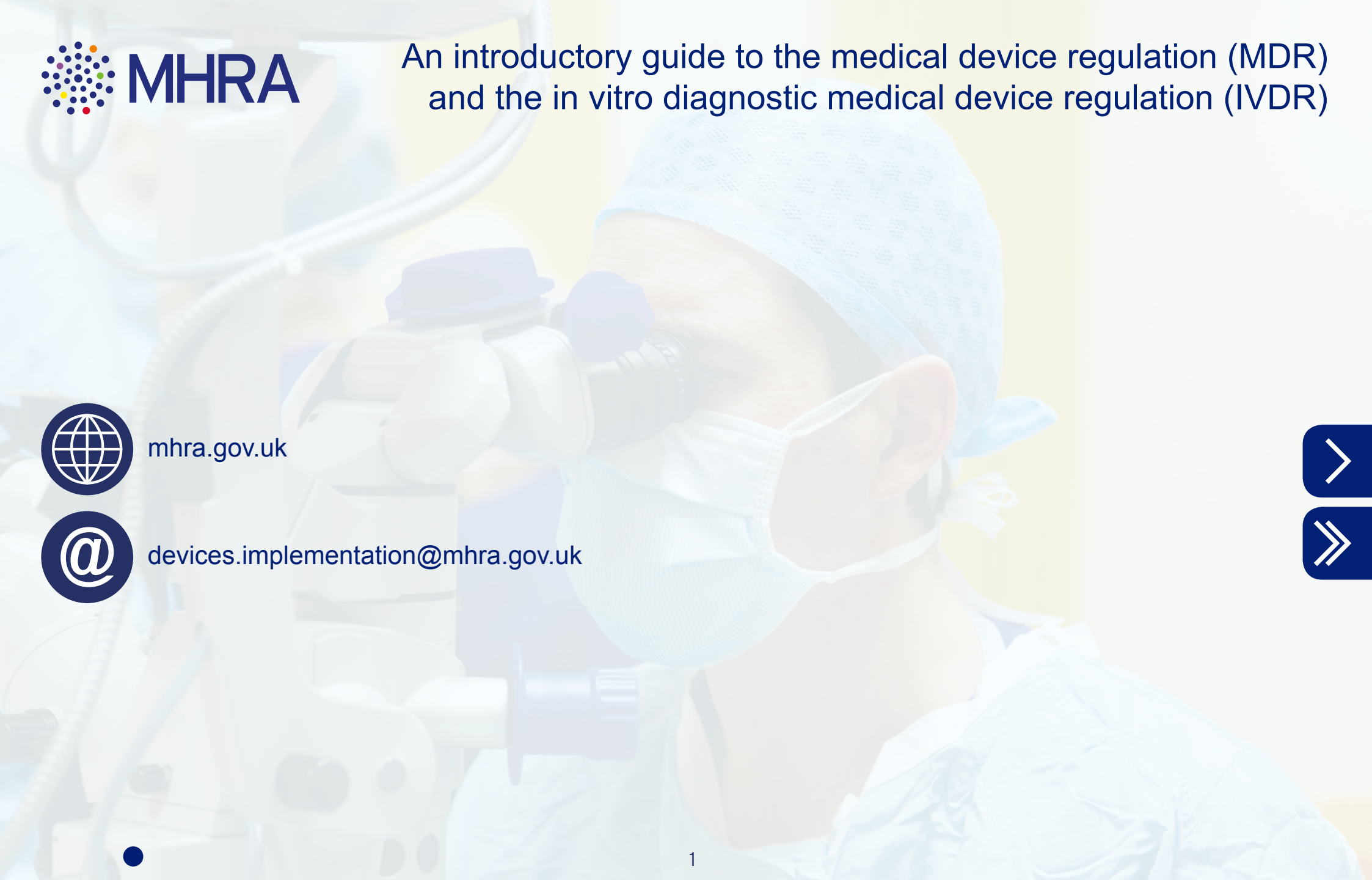
An introductory guide to the medical device regulation (MDR) and the in vitro diagnostic medical device regulation (IVDR)



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Navigate through the topics listed along the bottom of each page using the buttons on either side of the document.

You can use the arrow buttons to navigate through the pages one by one (you can also do this by using the left and right cursor buttons on your keyboard) or to jump to the first and last pages of the document (also controlled with the ‘Home’ and ‘End’ buttons on your keyboard).

Any words in Green can be clicked on to take you to the relevant external resource.

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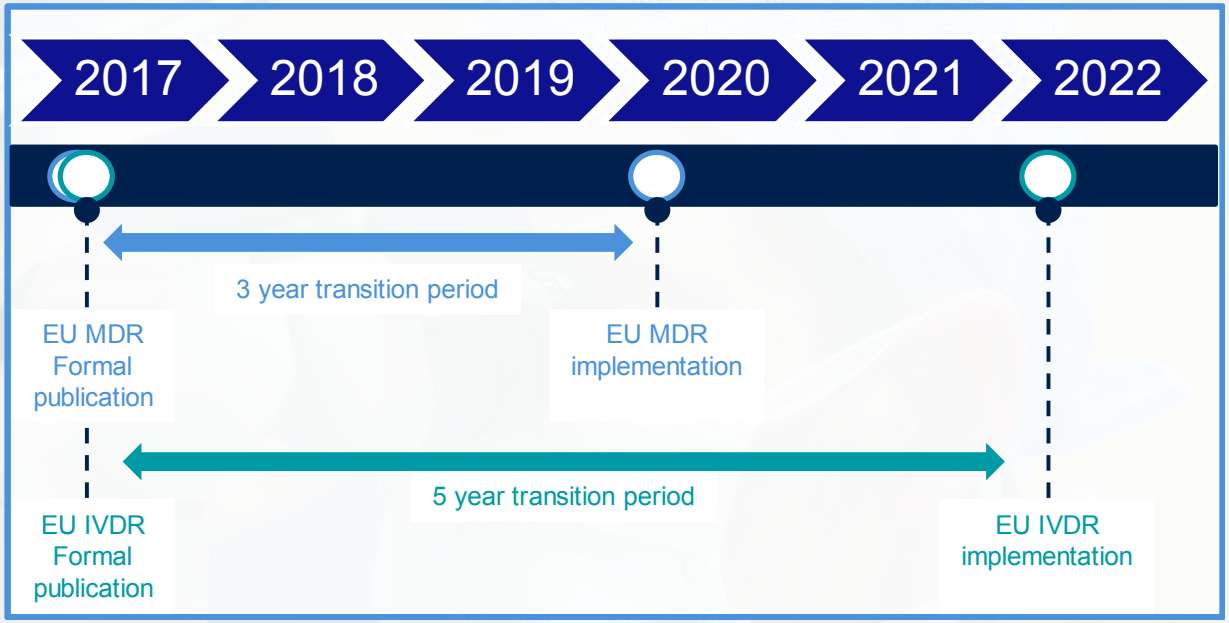


These Regulations entered into force on 25th May 2017.

However, most requirements will not fully apply until 26th May 2020 for Medical Devices, and 26th May 2022 for In Vitro Diagnostic Medical Devices.

Medical Device

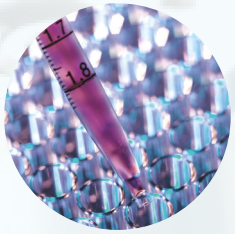
Examples:

- dental and surgical instruments
- bandages and splints
- treatment chairs and hospital beds

Definition*:

‘Medical device’ means any instrument, apparatus, appliance, software, implant, reagent, material or other article intended by the manufacturer to be used, alone or in combination, for human beings.

*A full definition can be found in Article 2(1) of the MDR.



In Vitro Diagnostic Medical Device

Examples:
- pregnancy tests
- blood glucose monitors

Definition*:
'In vitro diagnostic medical device' means any medical device which is a reagent, reagent product, calibrator, control material, kit, instrument, apparatus, piece of equipment, software or system, whether used alone or in combination, intended by the manufacturer to be used in vitro for the examination of specimens, including blood and tissue donations, derived from the human body.

*A full definition can be found in Article 2(2) of the IVDR

Borderline Products

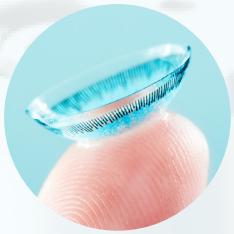
Examples:

- Medicated surgical dressings (medical device or medicinal product depending on manufacturer's claim)
- Head lice products (medical device or medicinal product depending on their mode of action)

Some products are hard to distinguish from a medicine or a medical device. These products are called borderline products until their status has been decided.

MHRA determines whether a product falls within the definition of a medicine – 'medicinal product' – or a medical device and provides information on whether a product is a medicine or a medical device or not.

For more information, please visit our website



Aesthetic Products

Examples:

- Non-corrective contact lenses
- Equipment for liposuction
- Equipment intended for brain stimulation

Definition:

Annex XVI of the MDR lists out groups of products without an intended medical purpose, which will now be regulated as medical devices

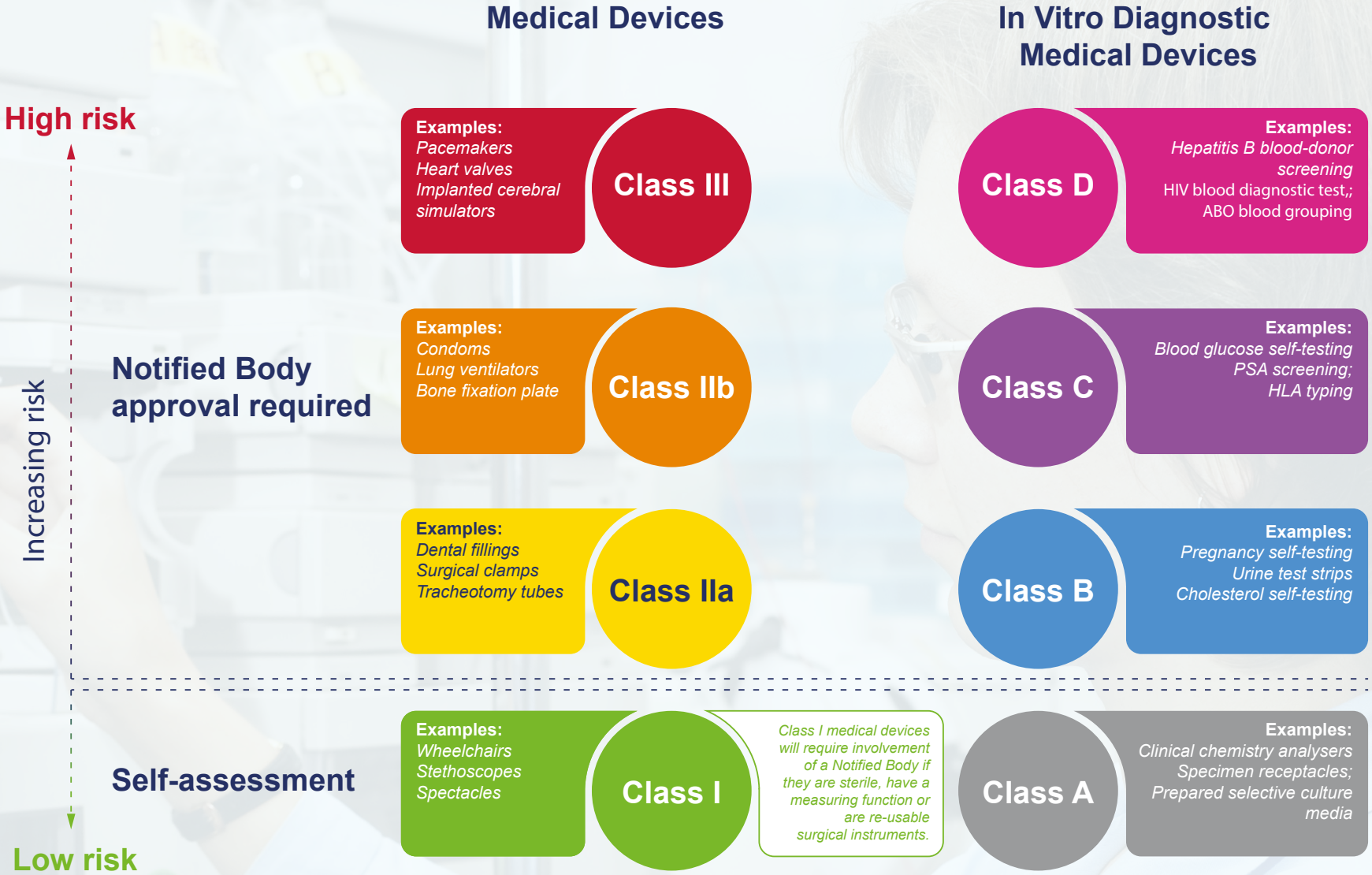
Manufacturers of products listed in Annex XVI of the MDR shall comply with the relevant common specifications* for those products.

*These common specifications are expected to be published by the Commission by 26th May 2020

Classification is based on risk, as set out in Annex VIII of the MDR and Annex VII of the IVDR.

Manufacturers need to demonstrate that their medical device meets the requirements in the MRD or IVDR by carrying out a conformity assessment. The assessment route depends on the classification of the device.

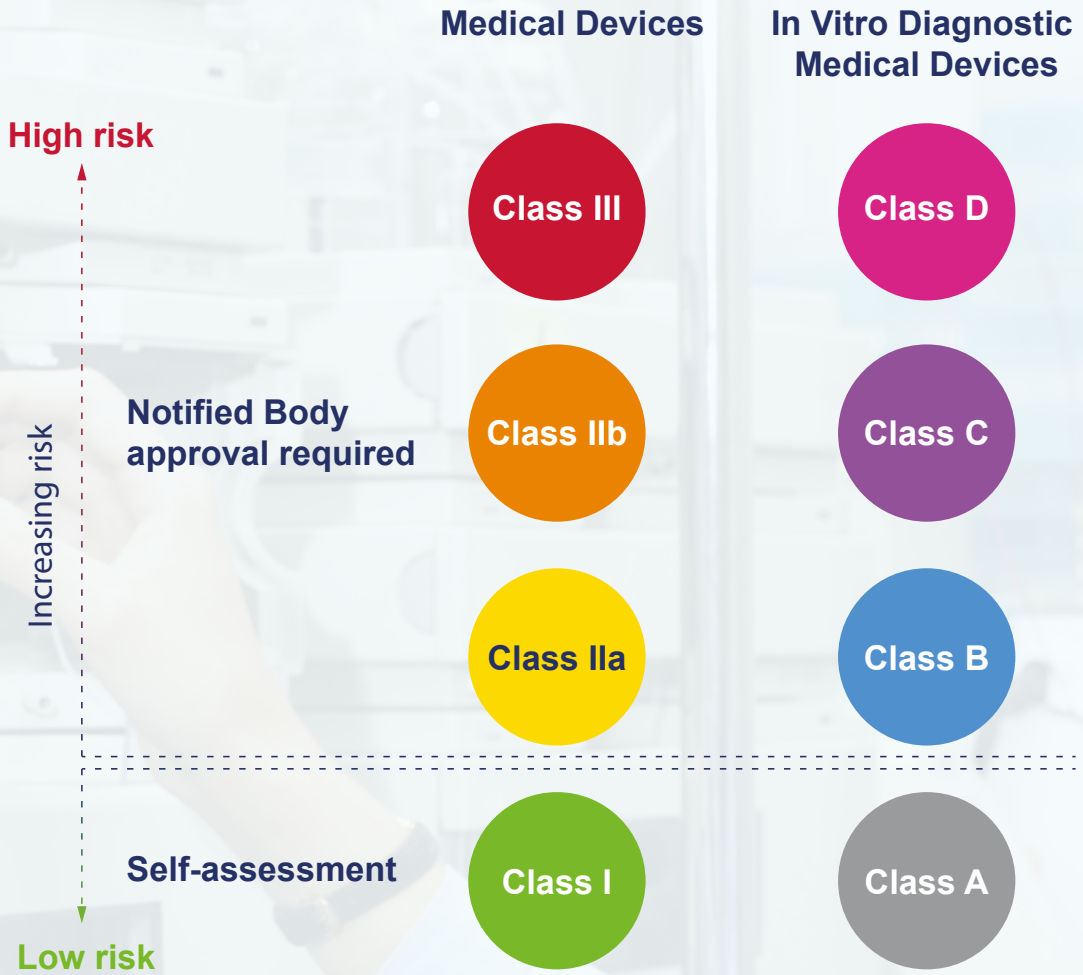
The risk class determines whether or not a conformity assessment would be required (which is done by a Notified Body).


Medical Devices
In Vitro Diagnostic Medical Devices
High risk
Increasing risk
Notified Body approval required
Self-assessment
Low risk
Examples:
Pacemakers
Heart valves
Implanted cerebral simulators
Class III
Examples:
Hepatitis B blood-donor screening
HIV blood diagnostic test,;
ABO blood grouping
Class D
Examples:
Condoms
Lung ventilators
Bone fixation plate
Class IIb
Examples:
Blood glucose self-testing
PSA screening;
HLA typing
Class C
Examples:
Dental fillings
Surgical clamps
Tracheotomy tubes
Class IIa
Examples:
Pregnancy self-testing
Urine test strips
Cholesterol self-testing
Class B
Examples:
Wheelchairs
Stethoscopes
Spectacles
Class I
Class I medical devices will require involvement of a Notified Body if they are sterile, have a measuring function or are re-usable surgical instruments.
Examples:
Clinical chemistry analysers
Specimen receptacles;
Prepared selective culture media
Class A

Conformity assessment

Manufacturers need to demonstrate that the medical device meets the requirements in the MDR or IVDR by carrying out a conformity assessment. The assessment route depends on the classification of the device.

Manufacturers can place a CE mark on the product to show that the medical device has met the requirements when it has passed the conformity assessment.

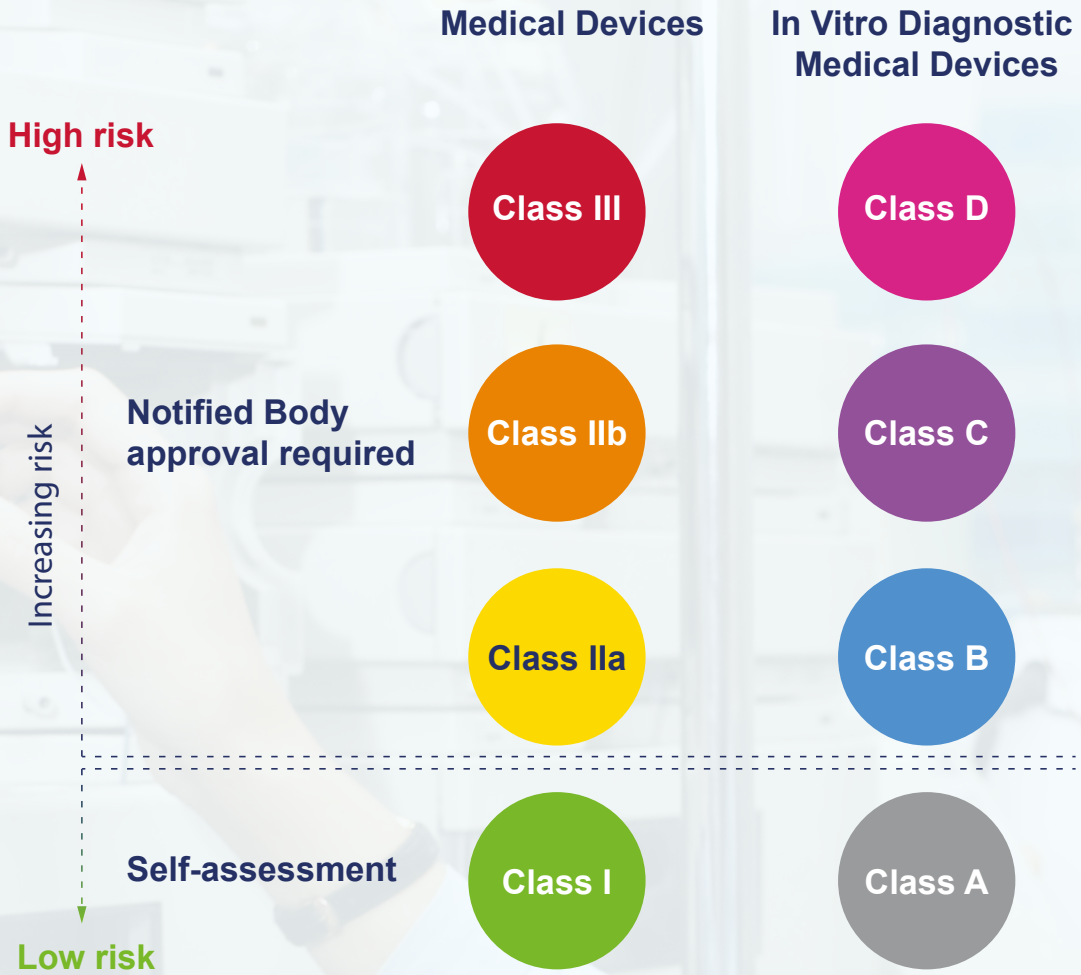


Which classes of products require conformity assessment by a notified body?

Approval is required for Class IIa, IIb and III medical devices and Class B, C and D in vitro diagnostic devices.

Some Class I and Class A devices will require notified body approval for parts of the manufacturing process that relates to sterility or metrology, if the medical device includes sterile products or a measuring function.

Manufacturers can certify their products with any notified body within the EU.



Notified Body

Notified bodies are independent certification bodies designated by national Competent Authority (i.e. MHRA). They perform third-party conformity assessment activities including calibration, testing, certification and inspection.

A list of active notified bodies can be found on NANDO.

What requirements do I need to meet for a conformity assessment?

1. General Safety and Performance Requirements (Annex I of the MDR and IVDR):

- Benefits must outweigh risks and achieve the claimed performance - This must be proven with supporting clinical evidence and investigation
- Chemical, physical and biological properties for medical devices
- Performance characteristics for in vitro diagnostic medical devices
- Information supplied by the manufacturer with the device - For example, instructions for use. It is important that devices are labelled correctly

2. Technical documentation (Annex II of the MDR and IVDR)

3. Harmonised standards / common specifications (Articles 8 and 9 of the MDR and IVDR)

Please see Annex IX, X and XI of the MDR and the IVDR for more information.

In what instances can I place a device on the market without undertaking an assessment of conformity?

In certain circumstances, a Competent Authority may authorise the placing on the market or putting into service a specific device that has not carried out the procedures referred to in Article 52 of the MDR or Article 48 of the IVDR.

This can happen in circumstances that are in the interest of public health or patient safety or health.

See Article 59 of the MDR and Article 54 of the IVDR for more information on when you can derogate from the conformity assessment procedures.

1. Pass a conformity assessment

This does not apply to most Class I medical devices and Class A in vitro diagnostic devices

2. Draw up a declaration of conformity (Annex IV of the MDR and IVDR)

3. Place a CE mark on the device

CE marks are not unique to medical devices

4. Assign a Basic UDI-DI and provide it to the UDI database

For devices other than custom-made devices

5. Submit key information about the manufacturer, and authorised representative and importer if applicable, to the electronic system (Eudamed)

For devices other than custom-made devices

6. Place your CE marked device anywhere in Europe or put your device into service

The UDI system provides a consistent and standard way to identify medical devices throughout their distribution and use by health care providers and patients. Most devices will be required to have a UDI on their label and packaging, and for certain devices, on the product itself.

‘Unique Device Identifier’ (‘UDI’) is a series of numbers that enables for the tracing of the manufacturer, device (UDI-DI number) and the unit of device production (UDI-PI number).

UDIs will be phased in over several years, starting with the highest risk devices, such as heart valves and pacemakers.

See Article 27 of the MDR and Article 24 of the IVDR for more information.

The European databank on medical devices (Eudamed), is a database that those who manufacture and supply medical devices, as well as Notified Bodies, health institutions and Competent Authorities, will have access to.

Using this system, those involved in manufacturing and supplying medical devices and IVDs will need to register their organisation and devices, upload relevant documentation, apply for clinical investigations and performance studies, and upload post-market surveillance documentation.

Eudamed is currently being overhauled for the new regulations to increase capabilities and allow wider access.

See Article 30* of the MDR and Article 27* of the IVDR for more information.

*These requirements will not apply if the necessary improvements to the Eudamed database are not completed on time.

"I'm a manufacturer"

"I'm an authorised representative"

"I'm an importer"

"I'm a distributor"

Manufacturer

Definition:

'Manufacturer' means a natural or legal person who manufactures or fully refurbishes a device or has a device designed, manufactured or fully refurbished, and markets that device under its name or trademark.

Obligations:

Manufacturers will have a number of additional obligations, including:

- Having at least one person responsible for regulatory compliance;
- Ensuring that sufficient financial coverage is in place;
- Ensuring that quality management systems meet the more stringent requirements.

For more details, see Article 10 of the MDR and the IVDR.

Authorised representative

Definition:

'Authorised representative' means any natural or legal person established within the Union who has received and accepted a written mandate from a manufacturer, located outside the Union, to act on the manufacturer's behalf in relation to specified tasks with regard to the latter's obligations under this Regulation.

Obligations:

Authorised representatives will have a number of additional obligations, including:

- Having at least one person responsible for regulatory compliance;
- Where the manufacturer is not established in a Member State and has not complied its obligations, the authorised representative shall be legally liable for defective devices on the same basis as, and jointly and severally with, the manufacturer, and will need to ensure that sufficient financial coverage is in place.

For more details, see Article 11 of the MDR and Article 12 of the the IVDR.

Importer

Definition:

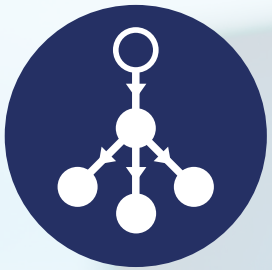
'Importer' means any natural or legal person established within the Union that places a device from a third country on the Union market.

Obligations:

Importers will have a number of additional obligations, including verifying that:

- The device has been CE marked;
- The manufacturer is identified and it has an authorised representative, if required;
- The device has been labelled correctly and a UDI has been assigned to the device;
- The device is registered in the electronic system (Eudamed).

For more details, see Article 13 of the MDR and the IVDR.



Distributor

Definition:

‘Distributor’ means any natural or legal person in the supply chain, other than the manufacturer or the importer, that makes a device available on the market, up until the point of putting into service.

Obligations:

Distributors will have a number of additional obligations, including verifying that:

- The device has been CE marked;
- The device is accompanied relevant information to be supplied by the manufacturer;
- The importer has complied with their general obligations;
- A UDI has been assigned to the device.

For more details, see Article 14 of the MDR and the IVDR.

Devices can also be offered by means of information society services. The obligations on these distributors are at Article 6 of the MDR and the IVDR.

Post-market surveillance requirements (preventative / proactive)

Definition:

'Post-market surveillance' means all activities carried out by manufacturers in cooperation with other economic operators to institute and keep up to date a systematic procedure to proactively collect and review experience gained from devices they place on the market, make available on the market or put into service for the purpose of identifying any need to immediately apply any necessary corrective or preventive actions.

Key obligations:

- Ensure ongoing safety of device – appropriate/risk benefit balance
- Inform development of future iterations of the device
- Conduct FSCAs (field safety corrective actions)

Field safety corrective actions are corrective actions taken by a manufacturer for technical or medical reasons to prevent or reduce the risk of a serious incident in relation to a device made available on the market.

Post-market surveillance requirements (preventative / proactive)

New features of the Regulations:

- PSURs - Periodic Safety Summary Report: Summarises the results and conclusions of the analyses of the post-market surveillance data. See Article 86 of the MDR and Article 81 of the IVDR
- PMCF / PMPF - Post-Market Clinical / Performance Follow-Up: A continuous process that updates the clinical / performance evaluation. See Annex XIV, Part B of the MDR and Annex XIII, Part B of the IVDR
- Other post-market studies

See Chapter VII, Section 1 of the MDR and IVDR for more information.

Vigilance requirements (reactive)

Key obligations:

- Reporting of serious incidents
- Voluntary and mandatory reporting
- Trend reporting

See Chapter VII, Section 2 of the MDR and IVDR for more information.

Serious incidents

A serious incident means any incident that directly or indirectly led, might have led or might lead to any of the following:

- the death of a patient, user or other person
- the temporary or permanent serious deterioration of a patient's, user's or other person's state of health
- a serious public health threat

Market surveillance

Definition:

‘Market surveillance’ means the activities carried out and measures taken by competent authorities to check and ensure that devices comply with the requirements set out in the relevant Union harmonisation legislation and do not endanger health, safety or any other aspect of public interest protection.

See Chapter VII, Section 3 of the MDR and IVDR for more information.

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