Regulatory Factsheet

# Regulation of medical and *in vitro* diagnostic medical devices in the UK (Great Britain and Northern Ireland)

## In the European Union (EU), medical and *in vitro* diagnostic medical devices are regulated by an EU framework that aims to ensure that all devices available for use on the EU market are safe and perform as intended.

Two new Regulations were introduced in April 2017:

- Regulation (EU) 2017/745 relating to medical devices (EU MDR) and
- Regulation (EU) 2017/746 relating to *in vitro* diagnostic medical devices (EU IVDR).

These replaced the previous directives:

- Directive 90/385/EEC on active implantable medical devices (EU AIMDD),
- Directive 93/42/EEC on medical devices (EU MDD), and
- Directive 98/79/EC on *in vitro* diagnostic medical devices (EU IVDD)

The EU MDR became fully applicable on 26 May 2021 and the EU IVDR became applicable as of 26 May 2022 in each EU member state.

In the United Kingdom (UK), devices are regulated under the Medical Devices Regulations 2002 (Statutory Instrument [SI] 2002 No 618, as amended) (the UK MDR 2002).

As a result of Brexit, the EU MDR and IVDR were not transposed into law, and therefore do not apply, in **Great Britain**. As such, UK law reflects the above EU directives (EU AIMDD, EU MDD, and the EU IVDD).

**It is important to be aware of the distinction between the United Kingdom (which is Great Britain and Northern Ireland) and Great Britain (which comprises England, Scotland and Wales)**. Thus, while the EU MDR and EU IVDR will not be implemented in England, Scotland and Wales, the EU rules will continue to apply for Northern Ireland.

Since 1 January 2021, there have been a number of changes, introduced through secondary legislation, to how medical devices are placed on the market in **Great Britain**.

### Summary of key requirements for placing a device on the Great Britain market

#### Registration of Devices

Registration with the UK Medicines and Healthcare products Regulatory Agency (MHRA) is essential prior to the placing on the market of any *in vitro* diagnostic medical devices (IVDs), custom made devices and systems or procedure packs in Great Britain.

#### Introduction of a UK Responsible Person (UKRP)

A UKRP (someone who acts on behalf of the manufacturer) is required if a medical device manufacturer is based outside the UK and wants to place a device on the Great Britain market.

#### **Product marking** UK Conformity Assessed (UKCA) marking

Manufacturers can use either the UKCA marking or the CE marking on devices they place on the Great Britain market until 30 June 2023. However, from this date the use of the UKCA product marking will be mandatory prior to placing a device on the market in Great Britain.

#### Recognition of CE marking

CE marking will continue to be recognised in Great Britain **until 30 June 2023.** Certificates issued by EU-recognised Notified Bodies (NBs) will continue to be valid for the Great Britain market until 30 June 2023. The EU no longer recognises UK NBs and as a result these UK NBs are not able to issue CE certificates and have become UK Approved Bodies.

## Registration of devices

In order for manufacturers to place devices on the UK market they are required to register with the MHRA, and all medical devices, including IVDs, custom-made devices and systems or procedure packs must be registered.

Registration requires information to be provided on the manufacturer, the device(s) and the UKRP (if applicable) using the online system for registering devices (MHRA Devices Online Registration System [DORS]).

In Great Britain, devices must conform to the UK MDR 2002, the EU MDR (until 30 June 2023), or the EU IVDR (until 30 June 2023) in order to be registered with the MHRA.

If a device has been CE marked under the EU MDD, EU AIMDD or EU IVDD it can continue to be accepted on the Great Britain market until 30 June 2023 (as long as the certificate remains valid for the EU market).

## UK Responsible Person (UKRP)

The MHRA will only accept registration of devices from manufacturers where the manufacturer is based in the UK. If a manufacturer is based outside the UK, **it must appoint a UKRP** who will assume certain responsibilities on behalf of the manufacturer, including registering the device with the MHRA.

### The Role of UKRP

**The UKRP:**

- Registers devices with MHRA
- Ensures that a declaration of conformity has been drawn up and ensures it is available for inspection by MHRA
- Ensures that the technical documentation has been drawn up and retains a copy of this documentation available for inspection by MHRA
- If applicable, ensures that appropriate conformity assessment has been carried out and retains a copy of any conformity assessment certificate available for inspection by MHRA
- Provides MHRA with, on request:
- information or documentation to demonstrate conformity of a device; or,
    - samples of devices or access to devices
    - cooperates with MHRA on actions to eliminate or mitigate risks posed by devices
    - informs the manufacturer about reports or complaints concerning suspected incidents associated with the devices for which they have been appointed.
    - terminates the relationship with the manufacturer and informs MHRA and any UK approved body (see below) that the relationship has been terminated if the manufacturer acts contrary to its obligations under the UK regulations.

Manufacturers of IVDs based outside the UK that are placing products on the market in Northern Ireland may also need to appoint a UKRP.

### UKCA mark

A UKCA mark is being introduced for certain goods being placed on the market in Great Britain for which European CE marking is applied and will apply to medical devices, including IVDs, in Great Britain.

The UKCA marking is not recognised in the EU, EEA or Northern Ireland markets so, for sales into these markets, CE marking is required.

Until 30 June 2023, medical device manufacturers can use either the UKCA marking or CE marking for devices to be placed on the Great Britain market. As of 1 July 2023, a UKCA marking will be required to place a device on the Great Britain market.

For Class I devices and general IVDs, it will be possible to self-certify against the UKCA mark. A UKCA certificate from a UK Approved Body will be required for higher-risk medical devices and IVDs.
It is vital that manufacturers and UKRPs develop plans for implementing the UKCA mark for their devices.