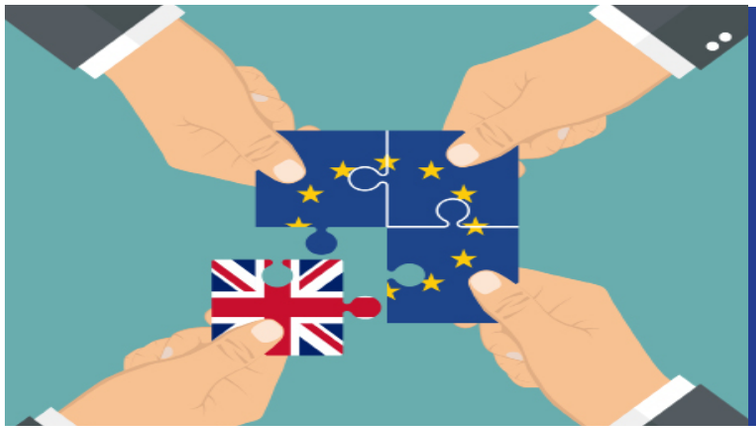

Accessing the UK Market

The UK Government has published a number of notices concerning the new regulatory system that will be put in place in the UK to replace the EU system currently operating there. This new regulatory system will come into operation on the 1 January 2021.

UK Regulations

Currently, the EU Directives for medical devices (Active Implantable Medical Devices Directive - AIMDD, Medical Devices – MDD & the In-vitro Diagnostic Medical Devices Directive – IVDD) are given effect in UK law through the Medical Devices Regulations 2002 (SI 2002 No 618, as amended). These UK Regulations will continue to have effect in Great Britain after 31 December 2020.

The Medical Devices Regulation (MDR) and In-vitro Diagnostic Regulation (IVDR) will not take effect until after the transition period with the EU has ended and will not be EU law automatically retained by the UK's EU Withdrawal Agreement Act. **They will, therefore, not automatically apply in Great Britain.**

Border controls

The UK Government has confirmed plans to introduce import controls on EU goods at the border after the transition period ends on 31 December 2020. This will mean traders will have to submit customs declarations and be liable to goods checks.

Prepare for border controls by making sure you have an Economic Operator Registration and Identification (EORI) number and also look into how you will make declarations, including using a customs agent. Further information on customs procedures can be found on the Revenue Commissioners website.

Information

Finally remind your UK customers that they will become 'importers' under UK law and they will be required to be able to access a copy of your product's technical file. You should prepare this information now so that it will be available to your UK customers.

Further information is available from the UK Government website (gov.uk/guidance/regulating-medical-devices-from-1-january-2021).

About NSAI

NSAI is an EU Notified Body for certification of medical devices, in vitro diagnostic devices, motor vehicles, construction products and measuring instruments. It also carries out market surveillance on packaged goods and measuring devices. NSAI aims to inspire consumer confidence and create the infrastructure for products and services to be recognised and relied on.

Contact Us

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Further Information

The Irish Government has a number of supports to help businesses across all sectors to prepare for Brexit.

Further information is available on the following websites:

- Government of Ireland: gov.ie
- NSAI: NSAI.ie
- Department of Business, Enterprise & Innovation: DBEI.ie
- Health Products Regulatory Authority: HPRA.ie

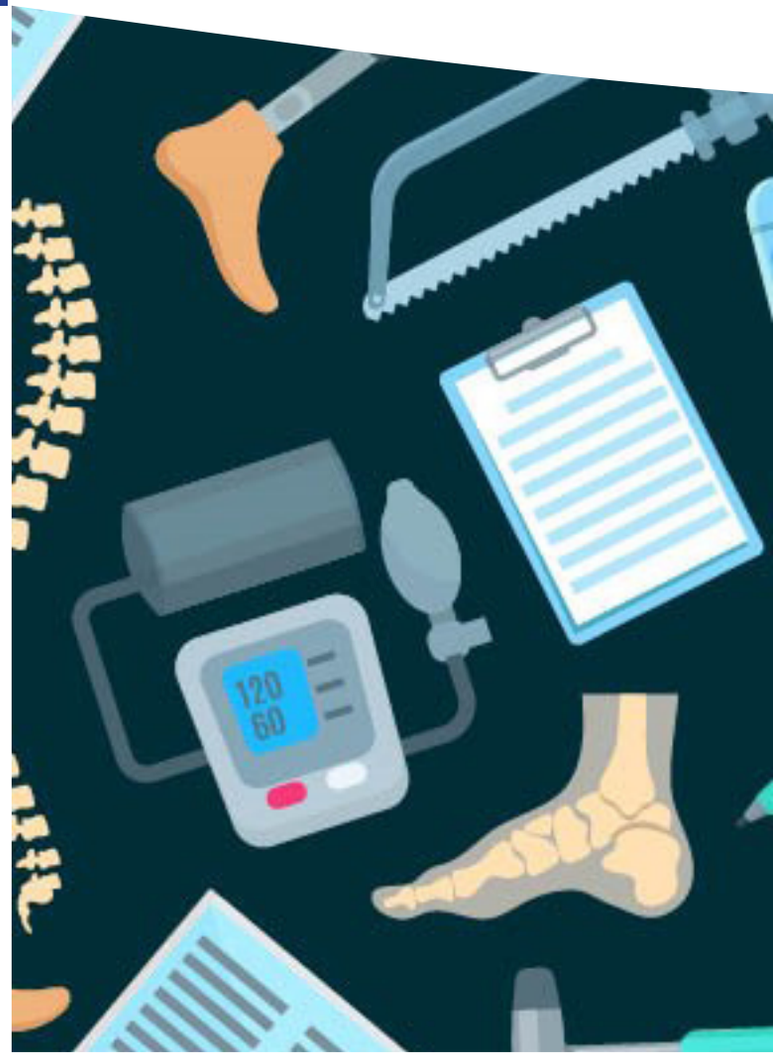
NSAI

Rialtas na hÉireann
Government of Ireland

Brexit Series

Medical Devices

Are you ready? 1.1.21



October 2020

Registrations in Great Britain

From 1 January 2021, any medical device, IVD or custom-made device will need to be registered with the MHRA before being placed on the Great Britain market.

- For the following devices, you will have 4 months to register with the MHRA (until 30 April 2021): Active implantable medical devices, Class III medical devices, Class IIb implantable medical devices & IVD List A
- For the following devices, you will have 8 months to register with the MHRA (until 31 August 2021): Class IIb non-implantable medical devices, Class IIa medical devices, IVD List B & Self-test IVDs
- For the following devices, you will have 12 months to register with the MHRA (until 31 December 2021): Class I medical devices & General IVDs

UK Responsible Person

Manufacturers based outside the UK will need to designate a UK Responsible Person that is established in the UK to place a device on the Great Britain market. The UK Responsible Person will act on behalf of the outside-UK manufacturer to carry out specified tasks in relation to the manufacturer's obligations which are set out in UK MDR 2002. This includes registering with the MHRA before the manufacturer's devices can be placed on the UK market.

CE marking

The MHRA will continue to recognise the CE mark for devices until 30 June 2023. This will apply to devices placed on the Great Britain market that have been CE marked under and fully conform with the Directive 90/385/EEC on active implantable medical devices (AIMDD), Directive 93/42/EEC on medical devices (MDD), Directive 98/79/EC on in vitro diagnostic medical devices (IVDD) & Regulation 2017/745 on medical devices (MDR) & Regulation 2017/746 on in vitro diagnostic medical devices (IVDR).

From 1 July 2023, new devices placed on the Great Britain market will need to conform with UKCA marking requirements.

If I rely on a UK Notified Body...

- Ask your UK NB if it moving to an EU-27 Member State
- If they are, transfer your certification to their new EU-27 NB
- If not moving, check the EU 'NANDO' website for a new EU-27 NB
- Engage with your new EU-27 NB about what you need to do
- If the medical device is CE marked by a UK based notified body you will not be able to place the product on the market after the 31st of December 2020

Do you import Medical Devices from the UK?

If you are currently a distributor importing products from the UK, you will continue to be a distributor during the transition period.

Irish based distributors sourcing devices from UK distributors or UK manufacturers post Brexit will become EU27 importers for devices they place on the EU27 market.

Responsibilities of an Importer

There are certain additional requirements which an importer must fulfil, and you should become familiar with these as soon as possible. Please refer to relevant Directives /regulation under "General obligations of importers".

Engage with the manufacturers of the products you import currently as a distributor. Ensure that you will be able to get the information and assurances you need to enable you to take on the responsibilities of an importer. These include:

- The medical device has been CE marked and that the EU declaration of conformity of device has been drawn up by the manufacturer.
- A manufacturer is identified and that an authorised representative has been designated by the manufacturer.
- Where applicable a unique device identifier (UDI) has been assigned by the manufacturer

Ensure that your details will be included in packaging and product information leaflets. You will be required to indicate:

- Your name
- Registered tradename or registered trademark
- The postal address at which you can be contacted
- Keep a copy of the EU declaration of conformity

Ensure that the technical documentation can be made available to market surveillance authorities for 10 years and 15 years in the case of implantable devices.

Trading with Northern Ireland

The Protocol on Ireland-Northern Ireland will apply on 1 January 2021. The Protocol provides that Northern Ireland is legally part of the UK customs territory but subject to certain provisions of EU law. These provisions are necessary to avoid a hard border on the island of Ireland. They include the Union Customs Code and EU legislation across a range of areas necessary to protect the integrity and operation of the Single Market in goods. Northern Ireland will remain aligned with the EU for medical devices.

Selling to NI

- You will be able to place products on the market in NI using your existing CE marking and Declaration of Conformity.
- You will not be required to provide any additional information to your customers.
- You will not require an EORI number or have to complete customs declarations.
- You will need to register your devices with the MHRA.

Buying from NI

- To place goods onto the Single Market, including in Ireland, it must have been certified by an EU Notifying Body. Certificates issued by notifying bodies in Northern Ireland are only valid in Northern Ireland.
- You will remain a distributor under EU law.
- You will not need to hold additional information from the manufacturer.
- You will not need to put your name and contact details on the imported products.
- You will not require an EORI number or have to complete customs declarations.

'CE UK(NI)' mark

The Protocol allows goods to be certified by NI notified bodies for the NI market. The conformity assessment of these devices will follow UK MDR 2002 in the form it exists in Northern Ireland and be marked with the 'CE UK(NI)' mark. Products carrying both the CE mark and UK (NI) mark can only be placed on the market in NI.