

Brexit Series

Medical Devices



September 2021

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 came into operation on the 1 January 2021.

UK Regulations

Products placed on the UK market are subject to UK legislation. The following EU Directives are given effect in UK law through the Medical Devices Regulations 2002 (SI 2002 No 618, as amended) (UK MDR 2002): Directive 90/385/EEC on active implantable medical devices, Directive 93/42/EEC on medical devices & Directive 98/79/EC on in vitro diagnostic medical devices. The UK MDR 2002 will continue to have effect in Great Britain after 31 December 2020.

You Must also register any medical device, IVD or custom-made device with the Medical and Health Products Regulatory Agency (MHRA) before placing it on the Great Britain market.

Until 30 June 2023 CE marked medical devices will still be allowed to be placed on the UK market.

Border controls

The UK Government has postponed the introduction of further import controls on EU goods moving into Great Britain. 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 are 'importers' under UK law and they are required to be able to access a copy of your product's technical file. You should now have this information available to your UK customers.

Further information is available from the UK Government website (gov.uk).

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.

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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](https://www.gov.ie)
- NSAI: [NSAI.ie](https://www.nsa.ie)
- Department of Enterprise, Trade and Employment: [enterprise.gov.ie](https://www.enterprise.gov.ie)
- Health Products Regulatory Authority: [HPRA.ie](https://www.hpra.ie)