



Brexit Series Medical Devices

Accessing the UK Market

For a time-limited period, CE marking will still be able to be used to access the UK market. The UK Government will decide when this concludes, after this point Irish manufacturers will no longer be able to access the UK market using their CE mark.

Post-Brexit, the UK's current participation in the European regulatory network for medical devices will end and the Medicines and Healthcare products Regulatory Agency (MHRA) will take on the responsibilities for the UK market.

The UK Government has indicated all medical devices, active implantable medical devices, in vitro diagnostic medical devices and custom-made devices will need to be registered with the MHRA prior to being placed on the UK market. There will be a grace period for this commensurate with the risk classification of the device or in vitro diagnostic device.

If a device manufacturer is not established in the UK, registration of a product with the MHRA must be undertaken by a 'UK Responsible Person' which is an entity that is established in the UK.

The UK will continue to accept labelling in the English language including information from other jurisdictions (such as Ireland), on condition that information complies with all UK requirements.

What you need to know

Earlier this year, the UK Government published legislation The Medical Devices (Amendment etc.) (EU Exit) Regulations 2019 which specifies that in the case of a disorderly Brexit, a UK regulatory system will be established which will mirror Regulations 2017/745 on medical devices (MDR) and 2017/746 on in vitro diagnostic medical devices (IVDR) and that the MHRA would become a standalone regulator outside the EU.

About NSAI

NSAI is an EU notified body for certification of medical 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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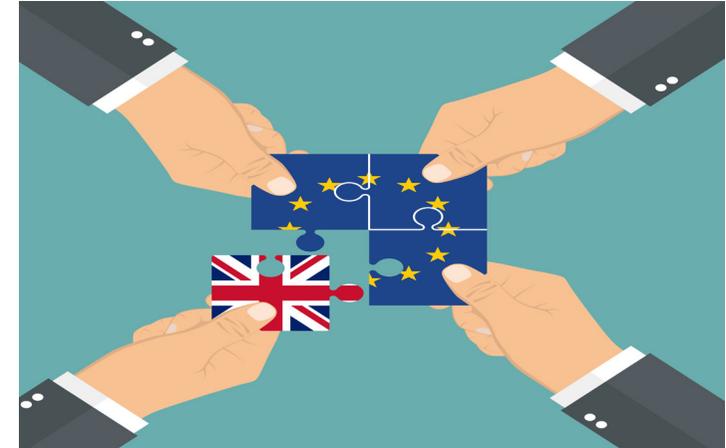
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Further information

The Irish Government has put in place a number of supports to help businesses, of all shapes and sizes and across all sectors to prepare for Brexit. Further information is available on the following websites:

- Government of Ireland
- NSAI
- Department of Business, Enterprise and Innovation





Product certification and economic operators

If you currently act as a distributor for a UK-based manufacturer you will assume the role of importer post-Brexit. The obligations for importers are outlined in the Medical Device Regulation.

Authorised representatives are required for all legal manufacturers who are not located in an EU Member State. UK-based Authorised representatives will no longer be recognised in order to access the EU market. UK manufacturers will likely need EU-based authorised representatives. The labelling requirements of moving an authorised representative may have significant adverse effects for supply chains. It is also a requirement that medical device label changes are notified to your respective notified body.

Rules of origin

If exporting to a third country where a Free Trade Agreement is in place, a preferential tariff rate may be applicable on products which have enough "EU content". Post-Brexit content from UK sources cannot be counted as "EU content".

Further information

In 2018, the EU Commission issued guidance related to industrial products including medical devices. It outlined the main implications for placing products on the EU market in the case of a disorderly Brexit.

Earlier this year, the European Commission published a Q&As related to medicinal products including medical devices.

Do you use a UK notified body for product certification?

All notified bodies in the UK will cease to be recognised as EU notified bodies and you will no longer be able to use them to place your product on the EU market.

All products certified by a UK notified body must be placed on the EU market before Brexit or they will need to undergo conformity assessment with a new notified body, this can be a long process and is dependent on the classification of the device and the quality of the supportive data.

A valid certificate from an EU -27 notified body is required after exit day for the placement of medical devices, active implantable devices and in vitro diagnostic devices onto the EU market. Manufacturers are advised to transfer to an EU 27 notified body for conformity assessment if they have not already done so.

Where a manufacturer has transferred from an UK notified body to any EU 27 notified body, products produced after the transfer must bear the new EU notified body number.

Placing your device on the market

Post-Brexit, your medical device can be assessed by an EU or EEA notified body and can be placed on the EU internal market and the UK market for a limited time.

What must I do now?

If I rely on a UK notified body...

- Check the EU 'NANDO' website to find another EU notified body to certify your product.
- Engage with your prospective notified body to see what you need to do to transfer certification.
- Arrange to have all products that are 'CE' marked by a UK notified body placed onto the EU market before Brexit.

If I am becoming an importer...

- Look at your supply chain.
- Find out the additional responsibilities you will be taking on.
- Engage with the manufacturers of the products which you import.
- Ensure that you will be able to obtain the information and assurances you need, to enable you to successfully take on the responsibilities of an importer.

Further information

The EU NANDO website provides a database of European Notified Bodies which have been designated to carry out conformity assessment tasks under EU product legislation.

For specific information about the various economic operators and their respective legal responsibilities, consult 'The 'Blue Guide' on the implementation of EU product rules.