Accessing the UK Market

The exact rules that will apply following the end of the transition period will depend on the details of any agreement between the EU and the UK concerning their future trading relationship or if no deal is agreed.

Free Trade agreement negotiations commenced in March 2020. The envisaged future partnership between the UK and the EU should contain regulatory cooperation in terms of technical regulation for placing medical devices on the EU market and in the UK. On the 20th February 2020 the UK Government introduced the Medicines and Medical Devices Bill.

After the end of the transition period all medical devices placed on the UK market must be registered with the UK Medicines and Healthcare Products Regulatory Agency (MHRA) and all medical device manufacturers who do not have a physical base in the UK will be required to assign a UK responsible person who will act on their behalf to carry out specific tasks to fulfil regulatory obligations.

There will be a grace period for both appointing a UK responsible person and registering your medical device with the MHRA. It ranges from 4 months for the highest risk devices to 12 months for the lowest risk devices. Further information is available from the UK Government website (gov.uk).

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.

Contact Us

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nsai.ie/Brexit

Further use of CE markings in the UK
(as stated by MHRA in January 2020)

You can use the CE marking if you’re placing certain goods on the UK or EU market until 1 January 2021.

The MHRA website will be updated if anything in relation to this changes.

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 and Innovation: DBEI.ie
- Health Products Regulatory Authority: HPRA.ie
Medical Device certification during the transition period

During the transition period, Union law will continue to apply in the UK. This means that the current rules regarding medical devices will continue to apply until the end of 2020, including:

- Certification by UK based Notified Bodies (NBs),
- Certificates of Free Sales (certificate for export) referring to a UK notified body or a UK based authorised representative.
- You can continue to use a UK notified body for CE marking purposes or a UK authorised representative
- You can continue to place medical devices on the UK Market using your existing certification

Status of a UK authorised representative

After the end of the transition period and depending on the details of any future agreement or if there is no agreement, UK based authorised representatives may no longer be able to fulfil the role of EU authorised representatives.

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.

What Must I Do Now?

If I rely on a UK Notified Body…

- Ask your UK notified body if it is establishing itself in an EU-27 Member State and prepare to transfer your certification to the new EU-27 based notified body.
- If yes engage with your UK notified body to see what you need to do to transfer certification to their new EU-27 notified body
- If no, check the EU Nando website to find another EU notified body to certify your product. This can be a long process and is dependent on the classification of the device and the quality of the supportive data. The details of all EU notified bodies are available on the EU Nando website.

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 identification number.

- Arrange to have all products CE marked by a UK notified body placed onto the EU market before the end of the transition period.

What you need to know during the transition period

- Your medical devices can be assessed by an EU notified body and placed on the UK market
- Your device can still be assessed by a UK notified body and placed on the UK and EU Markets
- UK based authorised representatives will continue to be recognised in the EU
- Check out the UK Government website for their latest updates.

How it works

EU Commission issues Directive
Government puts Directive into law
Competent Authority accredits Notified Body
Notified Body provides conformity assessment

*The manufacturer chooses a suitable notified body from those listed on the EU Nando site: ec.europa.eu/growth/tools-databases/nando/index