Brexit Factsheet: Medical Devices

Is your medical device business Brexit ready?

Since Ireland joined the EU Single Market, we have availed of the benefits that membership brings including the ease of trading in goods and services with our nearest neighbour- the United Kingdom (UK).

As the UK prepares to leave the EU, we must prepare for this transition. Post-Brexit, the UK will become a "third country" and trade in goods and services between the UK and the EU will be affected with impacts on both imported and exported goods. Below you will find some useful information on the changes in trading standards that will likely take place to both products and services post-Brexit.

What are the implications for medical device standards?

At this point in time, technical standard documents such as quality to ISO 13485 will remain the same post Brexit.

What are the implications for medical device certification?

Products Certification

- Post-Brexit, accreditation by UK based Notified Bodies will no longer be valid for products within the EU.
- If you or one of your product suppliers rely on a UK Notified Body for certification of conformity to support your product declaration for 'CE' marking purposes, you will need to hold certificates issued by an EU-27 Notified Body to demonstrate compliance for your products placed on the market 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.
- The EU commission 'NANDO' website provides a listing of all European wide Notified Bodies.
- For a time-limited period, you still will be able to access the UK market with 'CE' marking. 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.
- 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.
- Where a manufacturer has transferred from an UK Notified Body to EU 27 Notified Body, products produced after the transfer must bear the new EU Notified Body number.

The role of Authorised Representatives

- The duties of an "Authorised Representative" are set out in the existing directives and in the new regulations.
- It is the legal manufacturer of the specific medical device that is required to establish an "Authorised Representative" within a Member State, if they themselves are not located in a Member State.

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- UK based Authorised Representatives will no longer be recognised in order access the EU market and UK manufacturers will need EU 27 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.

For Irish importers and distributors who import product or materials from the UK

- If you currently act as a distributor for a UK-based manufacturer you will assume the role of importer post-Brexit.

- Post-Brexit, Irish importers of finished medical devices from UK manufacturers may be required to confirm the presence of an "Authorised Representative" in a EU-27 Member State.

Management System Certification

- It is expected that certification to any of the International Standards Organisations Management Systems Standards such as ISO 13485 or ISO 9001 will not be directly affected by Brexit. For Irish businesses under European Accreditation, the status of UK based certification to international standards may in time be impacted.

Looking for further information?

NSAI are currently notified for a range of product types across the following sectors- Construction, Medical Devices and Metrology. Within Medical Devices, NSAI are currently designated for a range of European Directives outlined below:

- Medical Devices Directive 93/42/EEC (MDD)
- Active Implantable Device Directive 90/385/EEC (AIMDD)
- In-Vitro Diagnostic Directive 98/79/EC (IVDD)

Contact the NSAI Brexit Unit at **BrexitUnit@NSAI.ie** for any queries on standards and certifications post-Brexit.

Websites	
NSAI	https://www.nsai.ie/brexit
Department of Business, Enterprise and Innovation	https://dbei.gov.ie/en/What-We-Do/EU-Internal-Market/Brexit/
Department of Foreign Affairs and Trade	https://www.dfa.ie/brexit/
Enterprise Ireland	https://www.prepareforbrexit.com/
InterTradeIreland	https://intertradeireland.com/brexit/
Irish Medtech Association	http://www.irishmedtechassoc.ie/Sectors/IMDA/IMDA.nsf/vPages/Home?OpenDocument
EU Commission NANDO website	http://ec.europa.eu/growth/tools-databases/nando/
EU Commission Information on Brexit	https://ec.europa.eu/info/brexit_en

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