NSAI

Rialtas na hÉireann
Government of Ireland

FAQs for Medical Devices

Are you ready? 1.1.21

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Brexit's impact on medical devices

The UK left the EU on 31 January 2020 under the terms of the Withdrawal Agreement and we are now in a transition period until 31 December 2020.

The Government decided on 29 May 2020 to intensify its readiness work on the basis of two scenarios: (i) a limited FTA (including fisheries), or, (ii) a hard Brexit with the EU and UK trading on WTO terms.

The UK will become a third country and whatever the shape of the future trading relationship with the UK, trading conditions will change and businesses need to prepare themselves for this.

The following EU rules concerning medical devices will continue to apply to all medical devices placed on the EU market:

- **Council Directive 90/385/EEC of 20 June 1990** on the approximation of the laws of the Member States relating to active implantable medical devices
- **Council Directive 93/42/EEC of 14 June 1993** concerning medical devices
- **Directive 98/79/EC of 27 October 1998** on *in vitro* diagnostic medical devices
- **Regulation (EU) 2017/745 of 5 April 2017** on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC
- **Regulation (EU) 2017/746 of 5 April 2017** on *in vitro* diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU

Products Imported from the UK

Question 1.
What rules will apply to products from the UK imported into Ireland?

Ireland is part of the EU market and all products imported from the UK will still need to conform to EU rules.

Any medical device imported from the UK which is currently required to be CE marked under EU rules will still be required to do so post Brexit if the device is being placed on the EU market.

This means that a medical device or in vitro diagnostic device will still require:

- An EU declaration of conformity
- CE marking
- Certification by an EU 27 notified body is applicable depending on classification of device.

Question 2.
How will Brexit impact my supply chain?

If you source products or components from UK based suppliers, then you will need to consider the impacts of new customs duties and potential supply disruption. Goods which originate from the UK may not be counted towards "EU content" under rules of origin, and this may impact your ability to access preferential tariff arrangements which the EU has in place with other jurisdictions.

All medical devices you source in the UK will still need to follow EU rules and be CE marked. If your suppliers rely on UK notified bodies for certification or conformity assessment, they will have to transfer to an EU-27 notified body before 31 December 2020. To eliminate any uncertainty concerning UK accredited test certificates any testing should be carried out by a test facility accredited in an EU-27 Member State.

It is recommended by the Health Products Regulatory Authority (HPRA) that you refrain from stockpiling medical devices, as this could have wider issues in terms of market supply. You should check the HPRA website regularly to ensure you have the most up to date information.

Product certification - third party certification & notified bodies

Question 3.
What should I do if I use a UK Notified Body to CE mark my device?

From the 1st January 2021 UK based notified bodies will cease to be recognised and their certificates will no longer be valid in the EU. You must have completed transferring to an EU notified body before the 31st December 2020.

Self-declaration is not affected. If the CE marking is based on self-declaration by the manufacturer, this will still be possible for UK manufacturers who export to the EU.

The details of all EU notified bodies are available on the EU Nando website.

Question 4.
I am a manufacturer of a product for which the certificate has been transferred from a UK notified body to an EU-27 notified body. Does the EU declaration of conformity and product labelling need to be updated to document this change?

Yes, both the EU declaration of conformity (drawn up by the manufacturer) and product labelling must be updated.

The EU declaration of conformity and notified body certificate of conformity will have to state that the certificate is now under the responsibility of the new EU-27 notified body and indicate both the old UK and new EU notified bodies details and identification numbers.

Question 5.
Does the notified body identification number on the device itself need to be changed also for products already on the market or manufactured before the transfer of the certificates has occurred?

Devices manufactured after the transfer of the certificate has taken place should be marked with the new EU-27 notified body identification number. Any devices certified by the UK notified body before the transfer of certification should be marked with the UK notified body identification number and can be placed on the EU market until 31st December 2020.

Economic Operators

Question 6.
How will I be impacted if I import products from a UK based manufacturer?

If you are currently a distributor sourcing products from the UK you will now become an importer.

There are certain additional requirements which an importer must fulfil, and you should become familiar with these as soon as possible. You can find more detailed information in article 13 of Regulation (EU) 2017/745 on medical devices.

Please refer to relevant Directives or Regulation under "General obligations of importers". Engage with the manufacturers of the products you import. 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.

You should engage with your UK suppliers to ensure you have all of the required information. The HPRA can also provide advice to Irish importers concerning their new responsibilities and requirements.

You should also engage with your UK suppliers as you shall require additional information and documents from them if you become an importer.

Question 7.
What additional responsibilities will I take on if I become an importer?

The additional responsibilities of an importer include:

- Before placing medical devices on the EU market you shall ensure that:
  - the appropriate conformity assessment procedure has been carried out by the manufacturer
  - the manufacturer has drawn up the technical documentation
  - the medical device bears the correct CE marking and is accompanied by the required documents
  - and that the manufacturer has complied with the requirements set out in the relevant directive and regulations.
- You will be required to indicate:
  - your name
  - registered trade name or registered trade mark
  - the postal address at which you can be contacted which shall be in English or Irish.

You will have to ensure that the medical device is accompanied by labels or instructions for use in the languages where the device is placed on the market.

You will be required to keep a copy of the EU declaration of conformity and ensure that the technical documentation can be made available to market surveillance authorities for 10 years and 15 years for implantable devices after the last device has been placed on the market.

General information on these obligations are given in Decision No 768/2008/EC of 9 July 2008 on a common framework for the marketing of products, and repealing Council Decision 93/465/ EEC, with more specific information given in the Active Implantable Medical Devices Directive (90/385/ EEC), Medical Devices Directive (93/42/EEC), In vitro Diagnostic Medical Devices Directive (98/79/EC), Medical Devices Regulation (2017/745/EU) and the In vitro Diagnostic Medical Devices Regulation (2017/746/EU).

Question 8.
I import products from outside the EU and the manufacturer has appointed a UK based authorised representative. What will be the impact for me?

From 1 January 2021, UK based authorised representatives will no longer be able to fulfil the role of EU authorised representatives. If the manufacturer's authorised representative is based in the UK, then they will need to appoint another authorised representative located in an EU-27 Member State and their name and address must be on the product label.

Exporting to the UK

Question 9.
What rules will apply in Great Britain from 1 January 2021?

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 (EU AIMDD)
- Directive 93/42/EEC on medical devices (EU MDD)
- Directive 98/79/EC on in vitro diagnostic medical devices (EU IVDD)

The UK MDR 2002 will continue to have effect in Great Britain after 31 December 2020.

The date of application of the medical devices regulation 2017/745 was postponed by 1 year on the 17th of April 2020 due to the global COVID-19 pandemic, the date of application of the IVDR 2017/746 is the 26th May 2022 as a consequence of this the medical devices regulation and the in vitro diagnostic regulation will not be EU law when the transition period ends and **will not apply in Great Britain.**

More information is available on the UK Government website:
gov.uk/guidance/register-medical-devices-to-place-on-the-market-from-1-january-2021

Question 10.
Will there be a new route to market for medical devices on January 1st 2021?

Yes, there will be a new route to market, the MHRA have indicated that UK notified bodies will automatically become UK approved bodies, but EU 27 notified bodies will have to apply for designation under the MHRA and obtain UKAS accreditation to become approved bodies in the UK.

The European Medical devices regulation will not be transposed into law once Brexit occurs and the MHRA have indicated that they will not be adopting the European medical devices regulation or the in vitro diagnostic regulation. The current legislation in Great Britain is the UK Medical Devices Regulation 2002 which is based on the medical devices directive, active implantable device directive and in- vitro diagnostic directive. The MHRA has indicated that they will be making changes to these directives in the future and will develop a new domestic regulatory framework for devices, where they will consider international standards, best practice and global harmonisation.

Question 11.
Will I have to register my medical devices if I want to place them on the Great Britain market?

From 1 January 2021, you will need to 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.

The MHRA is allowing a grace period for all devices to be registered with the MHRA and this grace period is based on classification of devices and is as follows:

Classification of Device	***Date when registration with the MHRA become mandatory***
Class III medical devices Class IIb Implantable medical devices Active implantable medical devices IVD List A products	1st May 2021
Class IIb non implantable medical devices Class IIa medical devices IVD List B products Self test IVDs	1st September 2021
Class I medical devices General IVD	1st January 2022

Question 12.
What is a UK Responsible Person?

This is a person or entity based in the UK who takes responsibility for the medical devices on the UK market, there are no specific requirements at this point apart from the necessity to have a UK address.

Manufacturers who are based outside the UK are required to appoint a UK based Responsible Person. The MHRA has recommended that the UK Responsible Person should be appointed prior to the 1st of January 2021.

A UK Responsible Person:

- Acts on behalf of the manufacturer who is based outside the UK
- Registers the medical device with the MHRA before the devices can be placed on the Great Britain market in line with the registration grace periods as mentioned above
- Must ensure the declaration of conformity and technical documentation have been drawn up and that there are appropriate conformity assessment procedures carried out by the manufacturer.
- In response to a request will provide the MHRA with all necessary information
- Provides samples of the device to the MHRA, or provide access to samples in the possession of the UK responsible person
- Co-operates with the MHRA on corrective and preventive actions to eliminate of minimise risks posed by the device
- Informs the manufacturer about complaints and vigilance reports
- Terminates the legal relationship if the manufacturer is acting contrary to the its obligations as set out in the UK Medical Devices Regulation 2002.

From the 1st January 2021, the name and address of the UK responsible person where applicable will need to be included on product labelling where the UKCA mark has been affixed.

UK responsible person details will not be required for CE marked devices.

More information available at:
gov.uk/guidance/regulating-medical-devices-from-1-january-2021#responsible

Question 13.
Can NSAI provide a list of UK Responsible Persons?

No, NSAI can not provide this. It is up to the individual manufacturers to elect their UK responsible person if they are continuing to place products on the UK market.

Question 14.
Can I still place CE marked devices on the Great Britain market?

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 following applicable EU legislation:

- Directive 90/385/EEC on active implantable medical devices (EU AIMDD)
- Directive 93/42/EEC on medical devices (EU MDD)
- Directive 98/79/EC on in vitro diagnostic medical devices (EU IVDD)
- Regulation 2017/745 on medical devices (EU MDR)
- Regulation 2017/746 on in vitro diagnostic medical devices (EU IVDR)

If you currently CE mark your medical device on the basis of self-certification, you will be able to continue to do so after 1 January 2021 and place your device on the Great Britain market until 30 June 2023.

This means that Irish medical device manufacturers can continue to place their devices on the Great Britain market using their existing CE marking until 30 June 2023.

Question 15.
What is the UKCA mark?

This is the new conformity assessment mark for UK product marking used for certain goods, medical devices, active implantable devices and in vitro diagnostic devices fall into this category of product.

The UKCA mark will not be recognised in the EU, EEA or Northern Ireland.

The UK CA mark is voluntary from the 1st January 2021 but will become mandatory from the 30th June 2023 for Medical devices and in Vitro Diagnostic devices.

Class I medical devices will be able to self certify to the UKCA mark from the 1st January 2021.

The UK CA mark will be based on the conformity assessment to the UK Medical Devices Regulation 2002 which is based on the medical devices directive, active implantable directive and in vitro diagnostic directive.

Question 16.
What rules apply in Northern Ireland?

Under the terms of the Northern Ireland Protocol, from 1 January 2021, the rules for placing medical devices on the Northern Ireland market will differ from those applicable to Great Britain. EU rules will continue to apply and you will need to CE mark with an EU 27 Notified Body.

Regulation 2017/745 on medical devices (EU MDR) and Regulation 2017/746 on in vitro diagnostic medical devices (EU IVDR) will apply in Northern Ireland from 26 May 2021, and 26 May 2022 respectively, in line with the EU's implementation timeline.

From 1 January 2021, most medical devices, in vitro diagnositic devices and custom-made devices will need to be registered with the MHRA before being placed on the Northern Ireland market.

Question 17.
Do devices need to be registered with the MHRA for Northern Ireland?

Yes, Registration of devices with the MHRA will be required according to the following schedule of note Class I medical devices and General IVDs need to be registered on the 1st January 2021.

Classification of Device	***Date when registration with the MHRA become mandatory***
Class I medical devices General IVD	1st January 2021
Class III medical devices Class IIb Implantable medical devices Active implantable medical devices IVD List A products	1st May 2021
Class IIb non implantable medical devices Class IIa medical devices IVD List B products Self test IVDs	1st September 2021

Please see the UK Government's guidance on registrations for more information:
gov.uk/guidance/register-as-a-manufacturer-to-sell-medical-devices

EU manufacturers (including Irish manufacturers) will be required to designate a UK Responsible Person before placing a Class I device, Class IIa device, Class IIb device, Class III device, Annex II List A IVD, Annex II List B IVD or self-test IVD on the Northern Ireland market. The UK Responsible Person will be required to register the device with the MHRA.

You can get more information from the UK Government website:
gov.uk/guidance/regulating-medical-devices-from-1-january-2021#NI

Question 18.
What are the requirements for a medical device manufacturer who wishes to place products on the EU market on the 1st January 2021?

1. Manufacturers and authorised representatives who wish to place products on the EU 27 market from the 1st January 2021 must have transitioned their certificate to an EU 27 notified body before the withdrawal date
2. Products manufactured after the transfer of certificates to the EU 27 notified body should bear the EU 27 CE mark
3. Manufacturers with a UK authorised representative must have transitioned to an EU 27 authorized representative before the date of withdrawal
4. Manufacturers and authorised representatives must ensure the labelling is in compliance with the requirements, an EU 27 notified body and or and EU authorised representative must be identified on the labelling
5. Manufacturers and authorised representatives must ensure documentation such as the declaration of conformity reflects the EU 27 notified body and EU authorised representative
6. Distributors sourcing devices from UK distributors or manufacturers will become EU 27 importers for devices they place on the EU market and will have to comply with obligations applicable to an importer.

Information

Question 19.
Where can I get more information?

Organisation	Website
Irish Government Brexit Portal	gov.ie/brexit
NSAI	nsai.ie/brexit
Health Products Regulatory Authority	hpra.ie/homepage/about-us/stakeholders/brexit/brexit---latest-information
InterTradeIreland	intertradeireland.com/Brexit
Enterprise Ireland	prepareforbrexit.com
Department of Enterprise, Trade and Employment	enterprise.gov.ie/en/What-We-Do/EU-Internal-Market/Brexit
Department of Foreign Affairs	dfa.ie/brexit
EU Commission Nando website	ec.europa.eu/growth/tools-databases/nando
EU Commission Information on Brexit	ec.europa.eu/info/brexit_en
EU Commission Brexit Preparedness Notices	ec.europa.eu/info/brexit-preparedness/brexit-notices-explanation_en
IBEC	ibec.ie/influencing-for-business/ibec-campaigns/brexit-and-the-future-of-europe
Irish Medtech Association	irishmedtechassoc.ie
UK Government Brexit information	gov.uk/transition

For further information please review the following:

- c.europa.eu/info/sites/info/files/brexit_files/info_site/com_2020_324_2_communication_from_commission_to_inst_en_0.pdf
- ec.europa.eu/info/sites/info/files/notice_to_stakeholders_industrial_products.pdf
- hpra.ie/homepage/about-us/stakeholders/brexit/medical-devices
- gov.uk/guidance/regulating-medical-devices-from-1-january-2021

Manufacturer's Checklist

Steps to take

- ☑ Check the certification status of all your medical devices
- ☑ Check the certification status of any component parts you may be sourcing and determine if Brexit will impact your supply chain
- ☑ Determine if Brexit will impact your ability to place products on the UK market

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