FAQs for Medical Devices during the transition period
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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 at least 31 December 2020.

The UK will continue to follow EU rules and the EU will continue to treat the UK as if it were a Member State during the transition period. There will be no immediate changes for citizens and businesses in their day-to-day dealings and the current rules regarding medical devices will continue to apply until the end of 2020, including certification by UK based notified bodies or Certificates of Free Sales when referring to a UK notified body or a UK based authorised representative.

During the transition period the EU and the UK will negotiate the agreements governing their future relationship with the aim of ratifying those agreements by the end of this transition period. Whatever the shape of the future trading relationship with the UK post transition, trading conditions with the UK will change and businesses need to prepare themselves for this change.

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

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 notified body.

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.

If your suppliers rely on certification or conformity assessment from UK based notified bodies or UK accredited test laboratories, you will need to enquire on how their certification is being impacted by Brexit.

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 (see link on Page 8).
Question 3.
How does the UK's withdrawal from the EU affect certification of medical devices by UK notified bodies?

Union law will continue to apply to medical devices and in vitro diagnostics lawfully placed on the UK or EU market. This means that the current rules regarding medical devices and in vitro diagnostics will continue to apply until the end of 2020, including: Certification by UK based notified bodies, Certificates of Free Sales (when referring to a UK notified body) or a UK based authorised representative.

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.

Question 4.
What should I do if I use a UK Notified Body to CE mark my device?

You can continue to use a UK notified body for CE marking purposes during the transition period. However, you should begin to prepare for the end of the transition period - ask your UK notified body if it is in the process of establishing itself in an EU-27 Member State and prepare to transfer your certification to the new EU-27 based notified body.

If they have no plans to move to an EU-27 Member State, you will need to find another EU-27 notified body to certify your device. The details of all EU notified bodies are available on the EU Nando website.

Question 5.
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. A 6 month labeling transition is allowed when a manufacturer transfers notified body.

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 6.
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?

If the device documentation is in order, there is no need to change the notified body identification number for products already placed on the EU market or manufactured before the transfer of certification has taken place and not yet placed on the EU market.

However, 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 still be placed on the EU market during the transition period.

Economic Operators

Question 7.
How will I be impacted if I import products from a UK based manufacturer?

If you are currently a distributor importing products from the UK you will continue to be a distributor during the transition period.

However, after the end of the transition period you may become an importer depending on the details of any future agreement or if there is no agreement. 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.

You should also engage with your UK suppliers as you shall require additional information and documents from them if you become an importer.
Question 8.
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.

• 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
  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 Direc-
tive (98/79/EC), Medical Devices Regulation (2017/745/EU) and the In vitro Diagnostic Medical

Question 9.
I import products from outside the EU and the manufacturer has appointed a UK based
authorised representative. What will be the impact for me?

As Union law will continue to have effect in the UK during the transition period the manufacturer
can continue to have a UK based authorised representative.

However, 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. If the manufacturer’s authorised representa-
tive is based in the UK, then they will need to appoint another authorised representative locat-
ed in an EU-27 Member State.
Exporting to the UK

**Question 10. How will Brexit impact my ability to place medical devices on the UK market?**

During the transition period Union law on medical devices will continue to apply in the UK. This means that you can continue to place medical devices on the UK market using your existing certification.

**Question 11. What rules will apply to medical devices in the UK after the end of the transition period?**

The exact rules that will apply 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.

The UK Government has indicated that CE marking will continue to be recognised by the UK for medical devices post-Brexit for a limited time period. They have confirmed that they will inform industry when the CE mark will no longer be accepted.

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 your behalf to carry out specific tasks to fulfil regulatory obligations. The requirement to have a UK responsible person established is in line with the grace period for registering your device with the Medicines and Healthcare Products Regulatory Agency (MHRA).

After the end of the transition period all medical devices placed on the UK market must be registered with the MHRA. This is done by the legal manufacturer of the medical device if that entity is based in the UK and if the legal manufacturer is not based in the UK then the responsibility for device registration is with the assigned UK Responsible Person.

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 (https://www.gov.uk/transition).

The Medical Devices (Amendment etc.) (EU Exit) Regulations 2019 and The Human Medicines (Amendment etc.) (EU Exit) (No. 2) and the Medical Devices (Amendment etc.) (EU Exit) (No. 2) Regulations 2019 amend the Medical Devices Regulations 2002. If you wish to continue exporting to the UK post-Brexit, you will need to familiarise yourself with the requirements of these regulations.
Information

Question 12.
Where can I get more information?

<table>
<thead>
<tr>
<th>Organisation</th>
<th>Website</th>
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<tbody>
<tr>
<td>Irish Government Brexit Portal</td>
<td><a href="http://www.gov.ie/brexit">www.gov.ie/brexit</a></td>
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<td>NSAI</td>
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<td>Enterprise Ireland</td>
<td><a href="http://www.prepareforbrexit.com">www.prepareforbrexit.com</a></td>
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<td>Department of Business, Enterprise and Innovation</td>
<td><a href="http://www.dbei.gov.ie/en/What-We-Do/EU-Internal-Market/Brexit">www.dbei.gov.ie/en/What-We-Do/EU-Internal-Market/Brexit</a></td>
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<tr>
<td>Department of Foreign Affairs and Trade</td>
<td><a href="http://www.dfa.ie/brexit">www.dfa.ie/brexit</a></td>
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<td>EU Commission Nando website</td>
<td>ec.europa.eu/growth/tools-databases/nando</td>
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<td>EU Commission Information on Brexit</td>
<td>ec.europa.eu/info/brexit_en</td>
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<td>EU Commission Brexit Preparedness Notices</td>
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<td>Irish Medtech Association</td>
<td><a href="http://www.irishmedtechassoc.ie">www.irishmedtechassoc.ie</a></td>
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<tr>
<td>UK Government Brexit information</td>
<td><a href="http://www.gov.uk/transition">www.gov.uk/transition</a></td>
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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
For more information, please visit:

NSAI.ie/Brexit