Medical Device Economic Operators

As you know from 1 January 2021, there will be new requirements for placing medical devices on the Great Britain (GB) and Northern Ireland (NI) markets, regardless of whether you are using a CE mark or UKCA mark.

These requirements and timelines will differ slightly depending on where you are based and what you already have in place. To support you with this we have pulled together a simplified list to help you check if you have everything you need in place to register your products and have sufficient legal presence in all necessary parts of the UK to legally place your products on the whole of the UK market GB or NI.

The legislation that will apply from 1 January 2021 will be the UK Medical Devices Regulation 2002 (No. 618) as amended by the Medical Devices (Amendment etc.) (EU Exit) Regulations 2020.

Registrations

Manufacturers, and legal representatives (UK Responsible persons and NI-based Authorised representatives) have registration commitments they must meet from the 1st January 2021, and these can differ between GB and NI.

Where you have a medical device that is already registered with the MHRA, it will not need to be re-registered. However, you or your UK Responsible Person or NI-Based EU Authorised Representative will be required to review the information held by MHRA to ensure it remains correct, in line with the registration grace periods.

For GB:

- ❑ From 1 January 2021, all medical devices, IVDs or custom-made devices will need to be registered with the MHRA, including any new devices being placed on the GB market. As this is an extension of existing registration requirements, there will be a grace period depending on the class of device to allow you time register.
- ❑ If you are a Manufacturer of Class I devices, custom-made devices and general IVDs and are currently required to register your devices with the MHRA (because you are based in the UK) you must continue to register your devices as you do now.

For NI:

- ❑ After the transition period, most medical devices, IVDs and custom-made devices that are placed on the Northern Ireland market will need to be registered with the MHRA. The precise requirements will depend on your location, the location of your Authorised Representative and the device class. There will be a grace period depending on the class of device to allow you time register.
- ❑ If your Authorised Representative is based in NI and you are therefore required to register Class I devices, custom-made devices and general IVDs currently with the MHRA you must continue to register your devices as you do now.

Legal presence

Both the UK and the EU have requirements for a regulatory presence to act on behalf of the manufacturer and undertake some of the manufacturer's responsibilities if they are based outside of each respective territory In the UK this is a UK Responsible Person. Under EU law

this is an EU Authorised Representative (NI will be applying EU rules under the Northern Ireland Protocol to the Withdrawal Agreement.)

You will need a UK Responsible Person if:

- ❑ you are based outside of the UK and want to sell in GB. For GB you should aim to designate a UK Responsible Person **as soon as possible from 1 January 2021** and they must be in place by the time you register your device
- ❑ you are based outside of the UK and want to sell in NI, and your Authorised Representative is based outside of NI. You must appoint a UK Responsible Person **by 1 January 2021** (except for where you will only place a Class I device, custom-made device or general IVD on the market that is registered with a different EU competent authority)

You will need an EU Authorised Representative if:

- ❑ you are based outside of NI or the EU. Your EU Authorised Representative can be based in NI or the EU and must be appointed **by 1 January 2021**. This means that manufacturers based in GB will require an EU Authorised Representative by 1 January 2021 to continue placing devices on the NI or EU markets.

Importers and distributers

The end of the transition period brings a number of changes if you are an importer or distributer of medical devices or in-vitro diagnostic devices that you need to be aware of for both NI and GB.

For GB:

- ❑ In cases where you are an importer and not the UK Responsible Person, you should inform the relevant UK Responsible Person of your intention to import a device. The UK Responsible Person is then responsible for providing the MHRA with a list of device importers if the manufacturer has not done so.

For NI:

- ❑ Currently when goods move into NI from GB, they are being distributed. From 1 January 2021, this changes, goods will be considered imported if they are brought into NI from either GB or another non-EEA country and placed on the NI market.
- ❑ If you are an importer you should inform the relevant NI-based Authorised Representative or UK Responsible Person of your intention to import a device. The NI-based Authorised Representative or UK Responsible Person will in turn be responsible for providing the MHRA with a list of device importers.
    - From 26 May 2021, and 26 May 2022 respectively the new EU Medical Devices Regulation 2017/745 (MDR) and the new *in vitro* Diagnostic Medical Devices Regulation 2017/746 (IVDR) will fully apply in NI. The MDR and IVDR place additional obligations on importers and distributors. Details of these requirements can be found Articles 13 and 14 of the Regulations. You can read more about the new Regulations here

Any more questions?

For further information on the regulation of medical devices at the end of the transition we strongly recommend you familiarise yourself with the MHRA's medical devices guidance for the 1 January 2021 and the MHRA's registrations guidance for the 1 January 2021.