Brexit and Manufacturers of Medical Devices

The notification of the United Kingdom ("UK") regarding the withdrawal from the European Union ("Brexit") will affect manufacturers of medical devices which are in possession of certificates issued by a notified body located in the UK or which have authorised representatives located in the UK. These companies need to anticipate the regulatory steps that will be carried out as a consequence of Brexit so that they can continue to operate and supply the EU market.

Manufacturers and Authorised Representatives in the UK

If the UK becomes a third country after Brexit, manufacturers and importers established in the UK will no longer be seen as economic operators under EU legislation. As a result, a distributor from one of the 27 EU Member States ("EU-27") will become an importer in terms of placing products from the UK on the Union market ("EU market"). Furthermore, the manufacturer established in the UK will need to designate an authorised representative in the EU-27. Other manufacturers outside the EU with a designated authorised representative in the UK will have to relocate their authorised representative to the EU-27.

Notified Bodies in the UK and Certificates

Based on Directive 93/42/EEC, to be replaced as of 26 May 2020 by Regulation (EU) 2017/745, manufacturers need to be in the possession of a certificate for most medical devices before these devices can be placed on the EU market. This certificate needs to be issued by a notified body of an EU-27 Member State. After Brexit, notified bodies established in the UK will be removed from the NANDO-database and therefore will no longer be recognized as notified bodies for the EU market.

As a consequence, the certificates issued by these notified bodies in the UK will become invalid for the EU market after Brexit. To ensure that the products can still be placed on the EU market, the manufacturers need to change the status of their certificates. Depending on the status of the certificate process for a medical device, the following steps need to be taken.

1. *The current certificate is issued by a notified body in the UK*

   Manufacturers can either apply for a new certificate at an EU-27 notified body or file a request at an EU-27 notified body to transfer the current certificate to an EU-27 Member State.

2. *Certificate not yet issued*

   Manufacturers need to apply for a certificate before the medical device can be placed on the EU market. Before Brexit, It is recommended to apply for a certificate at an EU-27 notified body to prevent the manufacturer from having to change its certificate again.

In all cases previously mentioned, it is possible to file a request for a new certificate or transfer the existing one to a Dutch notified body. Dutch notified bodies have extensive experience issuing certificates for medical devices. Regarding the (re)location of the authorised representative, manufacturers should also consider moving to the Netherlands. Since there is a competitive fiscal climate, the Netherlands is well connected and strategically located with a highly skilled multilingual workforce.

Regulatory climate in the Netherlands

Notified bodies

- DEKRA Certification B.V.
- DARE!! Certifications

Applicable national law and regulations

- Dutch Medical Devices Act
- Dutch Resolution on Medical Devices
- Code of Conduct Medical devices

Supervisor

- Dutch Healthcare Inspectorate (IGJ)

Upcoming processes

We can advise and assist manufacturers of medical devices with all the steps necessary to conform with current and future EU legislation. With our broad international network and experience, we can ensure that the abovementioned transfers of certificates and authorised representative are fully completed and implemented before 30 March 2019 so that the manufacturer can continue to operate and supply the EU market after Brexit.

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