HVG LAW

BREXIT

Manufacturers of Medical Devices

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Although the COVID-19 crisis will still have an impact in the coming period, we recommend that companies should prepare for Brexit. This is especially the case for manufacturers of medical devices which either hold certificates issued by a notified body located in the United Kingdom (**UK**) or 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 European Union (**EU**) market.

Manufacturers and Authorised Representatives

With Brexit, the UK will become a third country, which means 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 remaining 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 2021 by Regulation (EU) 2017/745, manufacturers need to hold a certificate for most medical devices before these devices can be placed on the EU market. This certificate must have been issued by a notified body of an EU Member State. After Brexit, notified bodies established in the UK will be removed from the NANDO-database and therefore will no longer be recognised 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. To ensure that the products can still be placed on the EU market, the manufacturers will need to change the status of their certificates. Depending on the status of the certificate process for a medical device, the following steps should be taken.

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

Manufacturers can either apply for a new certificate issued by 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. We recommend applying for a certificate issued by an EU-27 notified body before Brexit to prevent the manufacturer from having to change its certificate again.

Manufacturers that are certified by a notified body in the UK and that have not been transferred before Brexit, can apply for a derogation for the Netherlands. Manufacturers are only eligible for such a temporary exemption if they meet certain conditions. This derogation procedure applies only to the Netherlands and only for medical devices and in-vitro diagnostics.

In all the 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 location or relocation of the authorised representative, manufacturers should also consider moving to the Netherlands. With its competitive fiscal climate, the Netherlands is well connected and strategically located with a highly skilled multilingual workforce.

No intervention of a Notified Body required

Class I medical devices and all in-vitro diagnostics that have been put on the market via the UK, and where no notified body intervention is needed, have to be registered by the manufacturer's EU authorised representative with one of the EU-27 Competent Authorities. The Dutch competent authority is called Farmatec.

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Regulatory Climate in the Netherlands

Notified bodies
• DEKRA Certification B.V. • DARE!! Certifications
Dutch competent body
• Farmatec
Applicable national law and regulations
• Dutch Medical Devices Act • Dutch Resolution on Medical Devices • Code of Conduct Medical Devices • Directive 93/42/EEC
Supervisor
• Dutch Healthcare Inspectorate (IGJ)

Our added value

HVG Law has a team of experienced lawyers that can advise on any of the above in the run-up and aftermath of Brexit. Law Alerts on the effects of Brexit in fields other than healthcare law, such as privacy law, corporate and commercial law, financing and financial regulatory law and employment law can all be obtained from our lawyers.

What HVG Law can do for you

We deal with *all* matters that keep an organisation in good shape. From reorganisations to acquisitions, from compliance to litigation. You will be doing business with lawyers and civil-law notaries who work together.

With you and with each other, at the highest level. We advise *and* litigate.

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About HVG Law

HVG Law LLP (HVG Law) ranks amongst the top Dutch law firms and is characterized by an entrepreneurial , innovative and solution-driven approach. With more than 150 dedicated and pragmatic lawyers, including (candidate) Civil Law Notaries, HVG Law offers high-quality, legal services in a broad and multidisciplinary context. Our lawyers are active in all legal areas and sectors relevant to business, directors, shareholders and government authorities and have knowledge of your business and your market. At our offices in Amsterdam, Rotterdam, Utrecht, The Hague, Eindhoven, New York, Chicago and San Jose (i.e., Donahue & Partners LLP in the USA), we are able to offer our legal services to national and international clients. HVG Law is part of the global EY Law network and we have a strategic alliance in the Netherlands with Ernst & Young Belastingadviseurs LLP.

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