Special edition

UK Responsible Person

When the UK[1] leaves the European Union (without a deal), a new role created under the UK MDR 2002 (as amended by the UK MDR 2019) becomes mandatory for manufacturers of medical devices. Those manufacturers NOT established in the UK need to designate a 'UK Responsible Person' to act on their behalf and to legally place medical devices on the British market after Brexit[2].

Definition

According to the UK MDR 2019 the UK Responsible Person is defined as "a person established in the United Kingdom who acts on behalf of a manufacturer established outside the United Kingdom in relation to specified tasks with regard to the manufacturer's obligations under these regulations"[3].

Requirements

First of all, the term "person" means either an individual or a legal person (i.e. a company). When a company provides the service of "UK Responsible Person" the responsibilities fall to the whole company. Regarding the qualifications or the knowledge of the UK Responsible Person there aren't any specific requirements. "Only" competence in carrying out the necessary responsibilities is required (please refer to the next abstract for further information). The most important requirement is that the UK Responsible Person must be established and physically located in the UK. The registered business address will be used for official communications and you must be contactable at this address. Nevertheless, it is allowed to make use of resources based outside of the UK.

Responsibilities

The requirements of the UK Responsible Person are the same as for a European Authorized Representative. The UK Responsible Person must:

- ensure that the declaration of conformity and technical documentation have been drawn up and, where applicable, that an appropriate conformity assessment procedure has been carried out by the manufacturer
- keep available a copy of the technical documentation, a copy of the declaration of conformity and, if applicable, a copy of the relevant certificate, including any amendments and supplements for inspection by the MHRA[4]
- in response to a request from the MHRA, provide the MHRA with all the information and documentation necessary to demonstrate the conformity of a device

[1] United Kingdom
[2] British Exit from the European Union
[3] The Medical Devices (Amendment etc.) (EU Exit) Regulations 2019 PART 1 (3) (w) http://www.legislation.gov.uk/ukdsi/2019/9780111179260/pdfs/ukdsi_9780111179260_en.pdf
[4] UK Medicines and Healthcare products Regulatory Agency (UK Competent Authority)

- forward to the manufacturer any request by the MHRA for samples, or access to a device, and ensure that the MHRA receives the samples or has been given access to the device
- cooperate with the MHRA on any preventive or corrective action taken to eliminate or, if that is not possible, mitigate the risks posed by devices
- immediately inform the manufacturer about complaints and reports from healthcare professionals, patients and users about suspected incidents related to a device for which they have been designated
- terminate the legal relationship with the manufacturer if the manufacturer acts contrary to its obligations under these Regulations and inform the MHRA and, if applicable, the relevant notified body of that termination

Furthermore, the UK Responsible Person needs to register medical devices of overseas manufacturers with the MHRA before placing them on the UK market. If set out in the contract the UK Responsible Person can also be responsible for defined post-market surveillance tasks.

For further information relating to the requirements and responsibilities of the UK Responsible Person please follow this link: https://www.gov.uk/guidance/regulating-medical-devices-in-the-event-of-a-no-deal-scenario#uk-responsible-person

Registration Process with MHRA

After Brexit, ALL medical devices will need to be registered with the MHRA before placing on the UK market. Until May 2020 respectively 2022 it will be possible to register medical devices by using the GMDN Code. This will mean that it is possible to register groups of medical devices having the same GMDN Code. For class III medical devices, this is not possible. These devices need to be registered each for its own indicating the medical device name, model and catalogue or reference number. This will be the same case for all other medical devices after May 2020/2022 when the UK MDR 2019 comes into force simultaneously with the (EU) MDR.

The registration with the MHRA can only be submitted by UK manufacturers or UK Responsible Persons. The latter need to open up a single registration account for each manufacturer they represent. Within this process a product list including the products that should be registered as well as the referring GMDN code is required. If applicable, a copy of the CE certificate should be provided, either. Furthermore, documentary evidence supporting the position of the UK Responsible Person is required (letter of designation, signed contract) including company name and address of the manufacturer not located in the UK and its designated UK Responsible Person as well as the statement that the UK Responsible Person is acting with the consent of the overseas manufacturer and adheres to the legislation that applies for the devices being placed on the UK market. In addition, the UK Responsible Person needs to inform the MHRA about his registered place of business and contact details (and contact person if any) within the registration of a medical device. These contact details of the UK Responsible Person will be published within the Public Access Database for Medical Device Registration.

Grace Period

The grace period for manufacturers to have a UK Responsible Person available is the same as the grace period for the registration of devices with the MHRA:

4 months: class III medical devices, class IIb implantable medical devices, active implantable medical devices, IVD List A

8 months: class IIb non-implantable medical devices, class IIa medical devices, IVD List B, self-test IVDs

12 months: Class I medical devices, self-certified IVDs, class A IVDs

Fees

An initial registration application will cost £100. One application consists of products having the same GMDN code (until May 2020 respectively 2022). Adding products to an existing registration application or changes will also cost £100. It is mandatory to renew or confirm registrations one year after registration application and every two years after this date. For the renewing/confirmation additional £100 will be charged.

For further information relating to the registration process after Brexit, please follow this link: https://www.gov.uk/guidance/regulating-medical-devices-in-the-event-of-a-no-deal-scenario#registrations

Further requirements for manufacturers and importers

Manufacturers not established in the UK who need to designate a UK Responsible Person do not need to change the labeling of their products placed on the UK market. It is not mandatory to reflect the UK Responsible Person for a medical device on the labeling.

Importers who import medical devices to the UK market need to proof if a UK Responsible Person is established for the imported product and if the medical device is registered with the MHRA.

Additional information for manufacturers and importers can be found following this link: https://www.gov.uk/guidance/regulating-medical-devices-in-the-event-of-a-no-deal-scenario#role-of-those-manufacturing-and-supplying-devices

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