Special edition

UK Responsible Person / 英国责任人

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].

当英国1正式（无协议）脱欧时，按照2002年UK MDR法规（UK MDR 2019修订版）医疗器械制造商将被强制要求指定一个新的第三方。那些英国境外的制造商需要指定“英国责任人”以代表他们行事，并在英国脱欧2后使其医疗器械能合法地进入英国市场。

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].

定义

根据UK MDR 2019法规，英国责任人被定义为“在英国境内的个人或法人，其代表英国境外制造商执行法规所规定的制造商职责相关的特定事务。”

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

要求

首先，法规里术语“Person”是指个人或法人（即公司）。当一家公司提供“UK Responsible Person（英国责任人）”服务时，责任将落到整个公司。对英国责任人的资格或知识，没有任何具体要求。只要求具有履行必要职责的能力（请参阅下一个摘要以获取更多信息）。最重要的要求是英国责任人必须在英国设立并实质位于英国境内。注册的公司地址将用于官方通讯，必须可以通过该地址与厂商联系。但是，允许使用英国境外的资源。

[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

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
- 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

职责范围

英国责任人的职责要求与欧盟授权代表的要求相同。英国责任人必须：

-确保厂商签署了符合性声明并编写好技术文件，在适用的情况下，还应确认制造商进行了恰当的符合性评价程序

-保留技术文档的副本，符合性声明的副本以及相关证书的副本（如适用），包括任何修改和补充，供MHRA检查

-应MHRA的要求，向MHRA提供证明器械符合性所需的所有信息和文档

-向制造商转发MHRA对样品或器械的任何要求，并确保MHRA收到样品或已得到获取器械的渠道

-与MHRA合作采取任何预防或纠正措施，以消除或（如果不可能）减轻器械带来的风险

-如责任人代表的器械和疑似不良事故有关，则应立即把医护人员，患者或用户的投诉和报告告知给制造商

-如果制造商的行为违反了相关法规规定的职责，则应终止与制造商的法律关系，并通知MHRA，若适用，还应通知相关公告机构

[4] UK Medicines and Healthcare products Regulatory Agency (UK Competent Authority)

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.

此外，英国责任人需要在MHRA上注册境外制造商的医疗器械，然后才能将其投放到英国市场。如果合同中有约定，英国责任人还可以负责约定的上市后市场监督任务。

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

有关英国责任人的要求和责任的更多信息，请访问以下链接：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.

MHRA注册流程

英国脱欧后，所有医疗器械都要在MHRA进行注册，然后才能投放英国市场。分别在2020年（MDR）/2022年（IVDR）5月之前，可以使用GMDN代码注册医疗器械。这意味着具有相同GMDN代码的医疗器械可以注册在一起。但对于III类医疗器械，这是不可以的。这些器械需要分别注册，提交医疗器械的名称，型号和目录/参考编号。在2020/2022年5月UK MDR 2019与（EU）MDR同时生效后，所有其他非III类医疗器械也要按这样的方式注册。

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

MHRA的注册只能由英国制造商或英国责任人提交。后者需要为其代表的每个制造商开设一个注册帐户。在此过程中，需要一个产品列表，列出注册的产品及其GMDN代码。如适用，也应提交CE证书的副本。此外，还需要提供指定英国责任人的证明文件（指定信，签定的合同），其包括英国境外的制造商及其指定的英国责任人的公司名称和地址，以及英国责任人声明其经外国制造商同意的情况下行事，并遵守英国上市器械所适用的法律。此外，英国责任人需要在医疗器械注册过程中告知MHRA其自身的营业地址和联系方式（如有联系人，也要提供）。英国责任人的这些联系方式将在医疗器械注册的公共数据库中发布。

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

宽限期

制造商会有一个宽限期来指定英国责任人，这与向MHRA注册器械的宽限期相同：

4个月：	III类医疗器械，IIb类可植入医疗器械，有源可植入医疗器械，IVD清单A
8个月：	IIb类非植入医疗器械，IIa类医疗器械，IVD清单B，自我检测IVD
12个月：	I级医疗器械，自我认证的IVD，A类 IVD

费用

初次注册申请的费用为100英镑。一个注册申请只包含具有相同GMDN代码的产品（MD/IVD到2020/2022年5月）。将产品添加到现有注册中或更新注册也将花费100英镑。产品注册必须在递交后一年做更新或者确认，并在此日期后每两年再做更新或确认。更新/确认的额外费用为£100。

有关脱欧后的注册流程的更多信息，请访问以下链接：https://www.gov.uk/guidance/regulating-medical-devices-in-the-event-of-a-no-deal-scenario#registrations

对制造商和进口商的进一步要求

英国境外成立的制造商需要指定英国责任人，但无需更改其在英国市场上投放的产

products placed on the UK market. It is not mandatory to reflect the UK Responsible Person for a medical device on the labeling.

品标签。在标签上不强制要求印刷英国责任人。

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.

将医疗器械进口到英国市场的进口商需要确认该进口产品是否指定了英国责任人，以及该器械是否已在MHRA注册。

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

可通过以下链接获取制造商和进口商的其他信息：https://www.gov.uk/guidance/regulating-medical-devices-in-the-event-of-a-no-deal-scenario#role-of-those-manufacturing-and-supplying-devices

For more detailed information, please do not hesitate to contact us:
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