freyr®

UKRP Guide

United Kingdom
Responsible Person (UKRP)

From 01 January 2021 Non-UK Manufacturers will be required to appoint a UK Responsible Person (UKRP) established in the UK to place the products on UK Market.

The UKRP will act on behalf of the Non-UK manufacturer to carry out specified responsibilities includes registering the manufacturer's devices with the MHRA before the devices can be placed on the Great Britain market after CE Mark (until 30 June 2023) and UKCA mark.

Further, the UK Responsible Person Must

01

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.

02

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.

03

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.

04

Provide samples of a device to the MHRA or allow the MHRA access to the device where the UK Responsible Person has samples or access or, where they do not have access or samples, forward to the manufacturer any request from the MHRA for samples or access.

05

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.

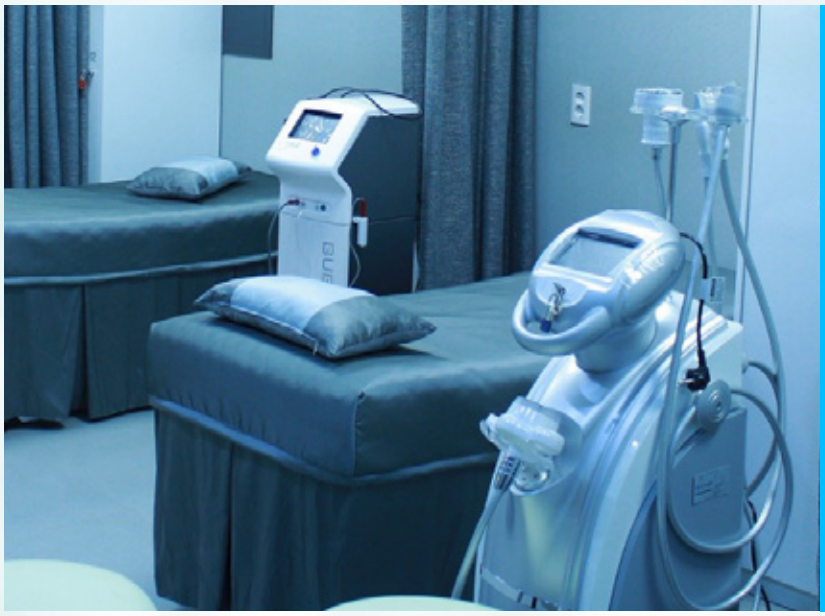
06

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.

07

Terminate the legal relationship with the manufacturer if the manufacturer acts contrary to its obligations under the applicable Regulations and inform the MHRA and, if applicable, the relevant Notified Body of that termination.

From 1 January 2021, CE marked medical devices can be continued to be placed on UK Market until 30 June 2023 and registered with MHRA as per the grace periods. The name and address of the UK Responsible Person for a Non-UK manufacturer, will need to be included on product labelling where the UKCA mark has been affixed.



MHRA Guidance Documents

1. MHRA Guidance on UKRP
2. MHRA Guidance on UKCA Mark
3. Approved Bodies in UK
4. Approved Bodies in UK MHRA Device Portal Registration
5. MHRA - Device portal login page
6. MHRA Guidance on Class I devices
7. MHRA - In vitro diagnostic medical devices: guidance on legislation
8. MHRA – guidance Virtual manufacturing of medical devices
9. MHRA -Guidance on the regulations for electronic instructions for use of medical devices MHRA
10. Guidance on post market surveillance of Medical devices in UK
11. MHRA Medical Device database
12. Medical Device Regulations 2002 (SI 2002 No 618,as amended) (UK MDR 2002)
13. Medicines and Medical Devices Bill

Contact details of MHRA

or further information, please email our Customer Services Centre at **info@mhra.gov.uk**

020 3080 6000 You can also **devices.regulatory@mhra.gov.uk** with questions.

Country Region
Specific Services

- Clinical Evaluation Report
- Global Regulatory Intelligence
- Medical Device Labeling & Review
- Staff Augmentation

A Leading, Global Regulatory
Solutions and Services Company

- Regulatory Strategy and Approach
- Translation Support
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- Design History File

Freyr is uniquely positioned to deploy best vertical/divisional in-house experts to provide the best Regulatory approach, specifically for combination product portfolio companies. The customized nature of Freyr services is synchronized keeping in mind our customers' growth strategy and product portfolio.

Freyr offers you a robust combination of technology and Regulatory expertise to ensure product continuity, label compliance, and data quality. We are committed to partnering with companies by providing strategic guidance as they develop, advance and innovate devices.

UKRP – Frequently Asked Questions

01

Who is an UKRP?

From Jan 1, 2021, non-UK manufacturers have to appoint a UKRP (United Kingdom Responsible Person) to register their Medical Devices/IVD products with the MHRA and place them in the UK.

02

What are the pre-requisites of a UKRP?

A UKRP can be an individual or a company established in the UK.

03

What are the responsibilities of a UKRP?

A UKRP shall act on the behalf of a foreign manufacturer and register the devices with the MHRA, before they are placed in the UK market. They shall ensure that the conformity assessment of the device has been completed by the manufacturer and the device technical documentations are available for the MHRA inspection, respond to the MHRA queries (query-response) and carry out Post marketing surveillance & related activities.

04

Why do you need a UKRP?

The non-UK manufacturer located outside the UK would require a UKRP to be appointed in the UK for registering their medical devices/IVD products with the MHRA and place them in the UK.

05

What products would require a UKRP?

Medical Devices (all classes) including Active implantable medical devices and In Vitro Diagnostic Devices.

06

How do you register with the MHRA?

A UKRP/UK based manufacturer will register the device on behalf of the manufacturer on the MHRA device portal. Freyr is already registered with the MHRA and holds a device registration account.

07

My product does not have an UKCA mark, do I need a UKRP?

Yes, in the UK you will need either a CE or an UKCA mark to place the product in the UK. A CE marked product is valid to be placed on the UK market till June 30, 2023 and a UKRP will need to be appointed, if the manufacturer is not based in the UK.

08

Do we need to include the details of a UKRP on the label?

Yes, if your product holds an UKCA mark and the manufacturer is not located in the UK, you will need to include the details of a UKRP on the label.

09

Does a UKRP requires to maintain a Quality Management System?

There is no mandatory requirement, but the MHRA expects you to process the PMS activities and manufacturer responsibilities. So, the understanding is, an organization should have a basic QMS system.

10

Our medical device products are CE marked and available in the UK. Do I need a UKRP?

Yes, the CE marked products are valid to be placed on the UK market until June 30, 2023 and would require a UKRP.

11

Where can I find more information about a UKRP?

The MHRA website provides all the details of a UKRP and the responsibilities of a UKRP are detailed in the SI-MDR 2002, as amended.

12

How long will it take to set up a UKRP for my products?

For one product, it takes roughly 48 hours.

13

How long will it take to set my distributor or importer to be a UKRP?

3-4 weeks.

14

What is a UKRP tool kit?

It is a folder with 10 separate documents required to set up the UK Distributor/Importer/manufacturer as a UKRP.

15

How long Freyr has been providing the UKRP services?

The UKRP Services are made available from Jan 1, 2021.

16

What are the critical steps to become a UKRP for a manufacturer?

Service agreement, letter of designation, review of technical documents and registration with the MHRA are some of the critical steps to be followed by a manufacturer to become a UKRP.

17

What happens if I change a UKRP?

You can change your UKRP at any given point of time and a UKRP would notify the MHRA about termination of services.

18

Can my distributor in the UK act as a UKRP?

Yes, Distributors/Importers can act as a UKRP.

19

What is the cost of a UKRP tool kit?

£199.00

20

When are the product labels required to be updated with a UK responsible person's details?

A UK responsible person's details are required only for an UKCA label.

About Freyr

Freyr is a leading, niche, end-to-end global Regulatory solutions and services company supporting large, mid, and small global organizations across different life sciences verticals - Pharmaceuticals | Medical Devices | Biotechnology | Biosimilars | Consumer Healthcare | Cosmetics | Food and Food Supplements | Generics | Chemicals. Freyr supports life sciences organizations in their entire Regulatory value chain -Intelligence Driven Submissions/Product Registrations | Labeling | Artwork | Post- Approval Change Management | Regulatory Software and other related services.

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