Medicines, medical devices and blood regulation and safety – guidance

Register as a manufacturer to sell medical devices

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Register a manufacturer or authorised representative (agent) for a manufacturer, to sell medical devices, including in vitro diagnostic (IVD) medical devices.

Contents

Overview

If you place certain medical devices on the EU market you or your authorised representative (agent) must be registered with the competent authority (national health regulator) in the EU state where you have an office or place of business. In the UK, Medicines and Healthcare Products Agency (MHRA) is the competent authority for the registration of medical devices. MHRA will only register manufacturers or authorised representatives that have a place of business in the UK.

Before you register, you must first complete a conformity assessment , so

you can put the CE marking on your products.

When you must register

You must inform a competent authority (in the UK this is the MHRA) when you first place your device on the market. You must register if you or your company sells, leases, lends or gifts:

- class I devices you have manufactured
- class I devices you have refurbished or re-labelled with your own name
- any system or procedure pack containing at least one medical device
- custom-made devices
- 'in vitro diagnostic medical device' (IVD) you have manufactured
- in vitro diagnostic medical devices (IVDs) undergoing performance evaluation

Note: We do not register devices classified as class IIa, IIb, III or active implantable devices. For these, you need to follow the appropriate conformity assessment route, which includes being assessed by a notified body.

Manufacturers without a place of business in the EU need to appoint an authorised representative in the EU. Only one authorised representative can be designated within the EU for each product type.

Eligible devices and their codes

Class I devices

Examples of class I devices include:

- dental and surgical instruments
- stethoscopes and ophthalmoscopes
- bandages and splints
- spectacle lenses and frames
- treatment chairs and hospital beds

Examples of products that are not medical devices include:

- toiletries
- tattooing instruments
- protective equipment
- swabs, wipes and disinfectants

The European Commission has a guidance document Definitions of "medical devices", "accessory" and "manufacturer" (MEDDEV 2.1/1).

Custom-made devices, systems and procedure packs

You will need to register if your company:

- places devices bearing the CE marking on the market, under your own name in a system or a procedure pack within their intended purposes and within the limits of uses specified by their original manufacturers
- sterilises, for the purpose of placing on the market under your own name, systems or procedure packs or other CE marked medical devices designed by the manufacturer to be sterilised before use

There is more information about custom-made devices and examples of the information we need on your statement on this page.

To register your medical device with the MHRA, you can use either of the following lists of codes:

- MHRA generic device description codes
- the Global Medical Devices Nomenclature System

In vitro diagnostic medical devices

Examples of in vitro diagnostic (IVD) medical devices include cultures, reagents, antigens, serums, plasmas etc and testing kits and equipment for these.

You will need to specify the correct codes for your IVD medical devices.

You can use either of the following lists of codes to register your IVD

device with the MHRA:

- the Global Medical Devices Nomenclature System
- the European Diagnostic Manufacturers Association (EDMA)

CE marking

The CE marking is a declaration of conformity with the EU's Medical Devices Directive (MDD).

For class I devices (those with the lowest risk level) you must ensure that your product complies with all the relevant essential requirements of the MDD and draw up a written statement to this effect (self-declaration).

If you manufacture sterile products or devices with a measuring function you must apply to a notified body for certification.

Once you are satisfied that your products meet all the relevant essential requirements, you can register with MHRA (or other EU authority), then you can put the CE mark on the product(s) and place them on the market.

Find out more about the conformity assessment for medical devices in section 2.5 of Guidance MEDDEVs on the European Commissions website.

Apply to register with the Device Online Registration System (DORS)

Using DORS you can register medical devices and IVD devices and manage your account details. First you need to create an account on DORS and wait for the email from us confirming that it is active before you can start registering your products.

Start the process on the device online registration system (DORS) and we will email you when it's activated.

You must pay £70 via DORS per registration.

There is more information about DORS here.

If you are an authorised representative (AR) of a non-EU manufacturer you must provide written evidence that you are acting with the consent of the manufacturer. We need an official letter, on headed paper, from the manufacturer stating your company's name and address – this is the designation letter.

If you are taking over the role from an existing authorised representative we need the designation letter and a copy of the letter cancelling the service with the previous representative.

The European Commission has guidance for authorised representatives.

Making changes to your DORS registration

You must inform MHRA, by updating your DORS record, if you want to change:

- address
- addition of device types
- manufacturer name
- authorised representative
- status of an IVD, for example a change from 'performance evaluation' to 'new'

You must pay £70 for each change request but you can change more than one detail within each registration request. We have to check these changes so they won't appear immediately in your DORS record.

Changes you can make for free by updating your DORS record include:

- removing a device from your records
- changing a contact person
- changing a telephone number and/or email address.

There is no need to tell us if you decide to sell extra products that fall

under the same generic product code you have already registered with us.

Register of manufacturers

Once registered, your company will be added to the Public Access Database for Medical Device Registration. Records are listed by manufacturer and device and include contact details. Manufacturers of in vitro diagnostic medical devices will not be published on this database, as the IVD Directive confidentiality clause still applies.

> Registering your devices with MHRA does not mean that we give you any form of accreditation, certification or approval for the device. It is just a notification of your activities.

Contact

If you are already registered with us, please contact us under the following alphabetical splits for your company name or the surname under which the registration is held, quoting your reference number:

- A – D Jasu Patel on 020 3080 7195
- E – M Barbara Clarke on 020 3080 7318
- N – Z Angela Bartley on 020 3080 7149

Email: mb-mda-era@mhra.gsi.gov.uk

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