



Guidance for products without an intended medical purpose

(Annex XVI)

under the new Medical Device Regulation (EU 2017/745)

How certain products without an intended medical purpose will be regulated as medical devices, and the impact that this will have on those manufacturing, importing, distributing, and using these products

Overview

Changes are coming to the way in which MHRA ensures the safety and quality of medical devices. A series of improvements are being made to modernise the current system that will ensure better protection of public health and patient safety.

The new Regulation for Medical Devices (MDR), which entered into force on 25th May 2017, will regulate certain groups of products without an intended medical purpose, listed under Annex XVI, as medical devices.

This means that, by 26th May 2020, certain groups of products, in line with all other medical devices, will be required to comply with the obligations set out in the MDR.

What is an Annex XVI product?

Annex XVI products are those for which a manufacturer claims only an aesthetic or another non-medical purpose but which are similar to medical devices in terms of functioning and risk profile.

These groups of products were included in the new Regulation to introduce requirements around the manufacturing and surveillance of these previously unregulated products to protect the health and safety of users.

The products are classed into six broad groups, listed below, with some examples to illustrate what may be included in each group. The European Commission has the power to amend this list to bring other products into scope.

	Group	Examples
1	Contact lenses or other items intended to be introduced into or onto the eye.	Non-prescription coloured contact lenses
2	Products intended to be totally or partially introduced into the human body through surgically invasive means for the purpose of modifying the anatomy or fixation of body parts with the exception of tattooing products and piercings.	Solid body contour modifying implant (e.g. horn implants)

3	Substances, combinations of substances, or items intended to be used for facial or other dermal or mucous membrane filling by subcutaneous, submucous or intradermal injection or other introduction, excluding those for tattooing.	Dermal fillers
4	Equipment intended to be used to reduce, remove or destroy adipose tissue, such as equipment for liposuction, lipolysis or lipoplasty.	Body sculpting equipment
5	High intensity electromagnetic radiation (e.g. infra-red, visible light and ultra-violet) emitting equipment intended for use on the human body, including coherent and non-coherent sources, monochromatic and broad spectrum, such as lasers and intense pulsed light equipment, for skin resurfacing, tattoo or hair removal or other skin treatment.	Intense pulsed light (IPL) machines for body hair removal
6	Equipment intended for brain stimulation that apply electrical currents or magnetic or electromagnetic fields that penetrate the cranium to modify neuronal activity in the brain.	Transcranial (non-surgically invasive) stimulation

How will this impact manufacturers of these products?

Manufacturers of Annex XVI products sold in Europe (including the UK) will have to be compliant with the requirements laid out in the MDR for general medical devices to ensure they are safe for use.

How to comply with the legal requirements

- 1 Identify which risk class your device falls into
- 2 Ensure your device complies with the MDR, as well as the common specifications for these groups of products (*see below*)
- 3 If required, pass a conformity assessment carried out by a notified body
- 4 Draw up a declaration of conformity and place a CE mark on the device
- 5 Assign a basic unique device identifier (UDI) and provide it to the UDI database
- 6 Submit key information about the manufacturer, and authorised representative and importer if the manufacturer is outside the EU, to the electronic system (Eudamed)
- 7 Place your CE marked device on the market, or put it into service, anywhere in Europe
- 8 Meet the post-market surveillance and vigilance requirements, such as conducting field safety corrective actions and reporting serious incidents to the competent authority (such as the MHRA)

For more information, please see our [guidance page](#).

Complying with common specifications

For the products covered by Annex XVI, the manufacturer will need to demonstrate compliance with common specifications. These common specifications will explain how these products can and should be assessed to demonstrate their safety and performance. The common specifications will address, at a minimum, the application of risk management. They may also cover clinical evaluation regarding safety.

Manufacturers of Annex XVI products will not need to comply with the Regulation until these common specifications have been adopted. However, adoption of these specifications is likely to be by 26 May 2020.

Manufacturer obligations

In addition to complying with the relevant common specifications, manufacturers of Annex XVI products will need to meet a number of other obligations. These include, but are not limited to, ensuring that:

- the device has been correctly classified against the new risk classification criteria (Annex VIII of the MDR);
- a person responsible for regulatory compliance is in place (Article 15 of the MDR);
- distributors and importers in the supply chain are compliant; sufficient financial coverage is in place, in respect of a manufacturer's potential liability (Article 10 of the MDR);
- the new vigilance reporting timescales are met and an annual periodic safety update report is created (Chapter VII, Section 1 and 2 of the MDR).

For further detail on manufacturer obligations, please read Article 10 of the [MDR](#).

How will this impact importers and distributors of these products?

The new Regulation sets out clear obligations that importers and distributors of medical devices must meet.

For further detail on these obligations, please read Articles 13 and 14 of the [MDR](#).

You can also read more about the impact that the MDR will have on importers and distributors on our [guidance page](#).

How will this impact users of these products?

For those who will use these products in either a **home or professional setting**, you will need to:

Source the device from a reputable supplier.

Before using the device, ensure you check the device is CE marked, in accordance with the MDR.



Report any suspected problem ('adverse incident') with a medical device using the Yellow Card Scheme as soon as possible, ensuring the report includes details of the device e.g. UDI.

See [link](#) to Yellow Card.

For those who will use these products within a **health institution¹ setting**, in addition to the above:

For devices that are Class III implantable devices, you will need to store and keep, preferably by electronic means, the unique device identifier of the devices.



You will need to provide patients who receive implantable Annex XVI devices, such as dermal fillers, with an implant card, as well as providing rapid access to certain information on the device.

¹ A health institution is defined as "an organisation the primary purpose of which is the care or treatment of patients or the promotion of public health" (ref. EU 2017/745, Article 2.36)