Health Institutions

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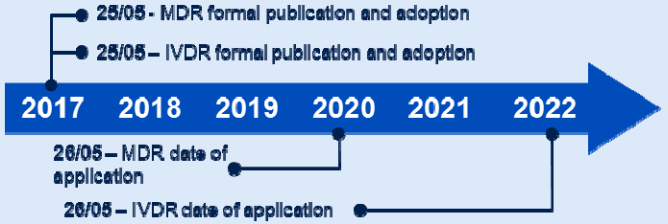
Background

The new Medical Device Regulation (MDR) and the In Vitro Diagnostic Medical Device Regulation (IVDR) entered into force on 25 May 2017. Once fully applied, they will replace the medical device, in vitro diagnostic medical device and active implantable medical device Directives.

The new regulations include obligations that health institutions will need to meet by 26 May 2020 for medical devices and 26 May 2022 for in vitro diagnostic devices. Health institutions are defined as “an organisation the primary purpose of which is the care or treatment of patients or the promotion of public health” (Article 2(36) of the MDR).The key requirements are listed below, with more details included in Articles referenced.

Timeline



Current situation

The current EU medical device and in vitro diagnostic medical device Directives (MDD and IVDD) do not apply to devices manufactured and used only within the same health institution and on the premises of their manufacture or used on premises in the immediate vicinity without having been transferred to another legal entity (in-house use).

Therefore, under the Directives, devices manufactured and used within health institutions are not considered as having been put into service and health institutions are exempt from the obligations set out in the Directives.

Key changes set out in the MDR and IVDR

Health institution exemption

(Article 5 of MDR / IVDR)

Devices that are manufactured or modified and used within health institutions shall be considered as having been put into service.

The requirements in the MDR/IVDR shall not apply to these devices provided that the certain conditions are met, including:

- Health institutions ensure that manufacturers follow the relevant general safety and performance requirements (Annex I);
- An appropriate quality management system is established;
- The health institution justifies that the target group’s specific needs cannot be met by an equivalent device on the market;
- Information is made available to competent authorities on request;
- A declaration with certain details is made publicly available;
- Reviews experience gained from clinical use of the devices and takes all necessary corrective actions.

Implant cards

(Article 18 of MDR)

Health institutions will need to provide patients with implantable devices with an implant card, which shall bear the patient’s identity, as well as rapid access to certain information, including:

- The identification of the device, including the device name, serial number, lot number, the UDI, the device model, and the name, address and website of the manufacturer;
- Warnings, precautions or measures to be taken by the patient or a healthcare professional;
- The expected lifetime of the device and any necessary follow-up.

Unique Device Identification

(Article 27 of MDR / Article 24 of the IVDR)

The UDI system will allow for things like safety alerts, potential recalls, as well as surveillance tasks more generally.

For Class III implantable medical devices, health institutions will need to store and keep preferably by electronic means the UDI of the devices which they have supplied or with which they have been supplied.

Health institutions may be required to do this for other devices also.

The UDI system will have a longer phase-in time (e.g. the requirement applies for class III and implantable devices in May 2021 and class A IVDs in May 2027).

Other changes

Clinical trial / performance studies – Article 73 of MDR / Article 69 of IVDR: significant alignment with the CTR, for example introducing damage compensation and a ‘Sponsor’.

Single-use devices and their reprocessing – Article 17 of MDR: may only take place where permitted by national law, but must meet certain conditions. The MHRA will consult on its current position on reprocessing.

3D printed devices – a case-by case assessment will be required to determine a product’s status and classification.

Software – classification rules will change with more software requiring notified body input.