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主旨：檢送歐盟新版醫療器材法規(Medical Devices Regulation, MDR)製造商應注意事項文件1份，請轉知貴會會員知悉，請查照。

說明：

一、依據駐歐盟兼駐比利時代表處經濟組110年3月5日比貿字第1100000145號函副本辦理。

二、為應MDR法規將於本年5月26日實施，歐盟執委會健康暨食品安全總署(DG SANTE)近期更新製造商應注意事項文件，包括醫療器材上市前應確認產品風險等級，及進行臨床與符合性評鑑等程序之扼要說明。

三、檢送前述文件影本1份供參，該文件可於歐盟官網下載，網址：https://ec.europa.eu/health/md_newregulations/publications_en。

正本：台灣醫療暨生技器材工業同業公會
副本：經濟部國際貿易局

署長 吳秀梅

European Commission

Factsheet for Manufacturers of Medical Devices

This Factsheet is aimed at manufacturers of medical devices. For a general overview of the impact of the In Vitro Medical Devices Regulation (IVDR) on manufacturers see the Factsheet for manufacturers of in vitro diagnostic medical devices. References to Annexes and Articles in this factsheet refer to the MDR (2017/745/EU).

MEDICAL DEVICES CHANGE OF LEGISLATION

What you need to know!

The new Medical Devices Regulation (2017/745/EU) (MDR) and the *In Vitro* Diagnostic Medical Devices Regulation (2017/746/EU) (IVDR) bring EU legislation into line with technical advances, changes in medical science, and progress in law making.

The new Regulations create a robust, transparent, and sustainable regulatory framework, recognised internationally, that improves clinical safety and creates fair market access for manufacturers.

In contrast to Directives, Regulations do not need to be transposed into national law. The MDR and the IVDR will therefore reduce the risks of discrepancies in interpretation across the EU market.

Transitional periods are planned to smooth the application of the new Regulations. However, you should bear in mind that consultants, in-house professionals, and Notified Bodies will all get busier as the deadline draws closer.

Act now to be ready on time!

Medical Devices Regulation (MDR) background

The MDR will replace the existing Medical Devices Directive (93/42/EEC) (MDD) and the Active Implantable Medical Devices Directive (90/385/EEC) (AIMDD). The MDR was published in May 2017, marking the start of a three-year period of transition from the MDD and the AIMDD.

During the transitional period the MDR will come into force gradually, starting with the provisions related to the designation of Notified Bodies and the ability of manufacturers to apply for new certificates under the MDR.

The transitional period will end on 26 May 2020, the "Date of Application" (DoA) of the Regulation. From that date the MDR will apply fully.

To avoid market disruption and allow a smooth transition from the Directives to the Regulation, several transitional provisions are in place (Article 120). Some devices with certificates issued under the Directives (AIMDD/MDD certificates) may continue to be placed on the market until 27 May 2024[1], and made available until 27 May 2025[2].

During the transition phase, products certified under the Directives and products certified under the Regulation will coexist on the market. Both will have equal status under the law, and no discrimination on eligibility criteria in public tenders may take place.

What has changed?

In terms of their impacts on manufacturers and products, the Directives and the MDR largely share the same basic regulatory requirements. No existing requirements have been removed, but the MDR adds new requirements.

Compared to the current Directives, the MDR places more emphasis on a life-cycle approach to safety, backed up by clinical data.

The MDR brings more stringent requirements for the designation of Notified Bodies, with increased control and monitoring by the national competent authorities and the Commission.

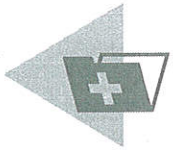
The MDR reclassifies certain devices and has a wider scope. For instance, the MDR explicitly covers all devices for cleaning, sterilising or disinfecting other medical devices (Article 2.1); reprocessed single-use medical devices (Article 17)[3]; and certain devices with no intended medical purpose (Annex XVI).

The MDR also covers internet sales of medical devices and medical devices used for diagnostic or therapeutic services offered at a distance (Article 6).

The MDR introduces a clinical evaluation consultation procedure for some Class IIb devices and for implantable Class III devices by an independent expert panel (Article 54).

A new Unique Device Identification system (Article 27) will significantly enhance the traceability and the effectiveness of post-market safety-related activities.

The MDR will also provide increased transparency, with information on devices and studies being made public. The new European Database for Medical Devices – EUDAMED – will play a central role in making data available and increasing both the quantity and quality of data (Article 33).



What does this mean in practice?

Scope (Article 1)

The scope of the MDR has broadened, so as a manufacturer you must check your product portfolios to find out whether more of your devices fall within the scope of the Regulation compared to the Directives. Pay attention to products listed in Annex XVI, which will be covered by the Regulation once the respective Implementing Regulation setting out common specifications has been adopted. The list of products excluded from the scope can be found in paragraph 6. Some products that combined a medical device and an *in vitro* diagnostic device or a medicinal product follow specific rules (see paragraphs 7, 8, 9).

It is now explicit that devices and services sold online fall under the scope of this Regulation (Article 6).

Definitions (Article 2)

The definition of a medical device has been slightly modified and there are more definitions of terms in the Regulation than in the Directives, in order to ensure a common understanding at EU level. Examples include: Unique Device Identifier (Definition 15), clinical data (Definition 48), clinical evidence (Definition 51), and serious incident (Definition 65).

Obligations of manufacturers

The obligations of the different actors and their relations are now clearly stated in the Regulation.

According to Article 10, manufacturers shall have systems for risk management (paragraph 2) and quality management (paragraph 9); conduct clinical evaluations (paragraph 3); compile technical documentation (paragraph 4); and apply a conformity assessment procedure (paragraph 6). Manufacturers are also responsible for their devices once they are on the market (paragraphs 12, 13, 14). They must have systems in place to cover their financial responsibility for harm caused by defective devices (paragraph 16).

Every manufacturer shall have a named person responsible for regulatory compliance (Article 15).

Manufacturers of some implantable devices will have to provide an implant card for the patient (Article 18).

Once they have completed all these obligations, manufacturers shall draw up a declaration of conformity (Article 19) and apply CE marking to their devices (Article 20).

Manufacturers outside the EU/EEA shall have a contract with an authorised representative inside the EU/EEA[4] (Article 11).

1 For definition see Article 2 paragraph 282
2 For definition see Article 2 paragraph 27
3 Reprocessing and further use of single-use devices may only take place where permitted by national law and only in accordance with this Article.
4 EEA: European Economic Area

The obligations of authorised representatives (Article 11), importers (Article 13) and distributors (Article 14) are also clearly described.

Risk classes of devices

As a manufacturer you must check your portfolio of products to determine whether some of your devices will be reclassified or will need to be scrutinised by a Notified Body. Determining the risk class of a medical device is essential in specifying the steps required for CE marking (Article 51), especially in terms of the choice of conformity assessment procedure and clinical requirements.

The MDR sets out 22 rules for determining risk classes (Annex VIII), compared to 18 rules under the Directive. You should pay special attention to rules regarding: invasive devices, surgically invasive devices and implantable devices (Section 5: Rules 5 to 8); active devices (Section 6: Rules 9 to 13, for example, software now falls under Rule 11); devices utilising tissues and cells (Rule 18); devices incorporating nanomaterials (Rule 19); and devices composed of substances (Rule 21).

Notified Bodies (Chapter IV)

Notified Bodies have to be designated under the new Regulation. They will be required to meet more stringent criteria, particularly in terms of clinical competence. Notified Bodies can apply to be designated from 26 November 2017. The process of designation, which might take 12 months or more, involves assessors from both national and European authorities. This means that the first Notified Bodies designated under the new Regulation might be available by the beginning of 2019.

The database of Notified Bodies (NANDO) can be found here.

http://ec.europa.eu/growth/tools-databases/nando/

As a manufacturer you must verify whether your Notified Body will be designated under the new Regulation and whether the scope of its designation will cover all your products. You must also start working with your Notified Body to plan the timing of certification for your product portfolio, taking into account the availability of your Notified Body, the need for additional data on devices and the transitional provisions in the new Regulation.

Device identification

A system of unique device identifiers (UDIs) will enhance the identification (Article 27) and traceability (Article 25) of MDs. This is a completely new feature of the Regulation.

Each MD – and as applicable, each package – will have a UDI composed of two parts: a device identifier (UDI-DI) specific to a device, and a production identifier (UDI-PI) to identify the unit producing the device.

Manufacturers are responsible for entering the necessary data on the European database (EUDAMED), which includes the UDI database, and for keeping it up to date.

Conformity assessment (Chapter V Section 2)

The assessment of the conformity of a device for CE marking varies according to the risk class and specific features of certain devices (Article 52). The intervention of a Notified Body is needed for all Class IIa, IIb and III devices, as well as some specific Class I devices (see paragraphs 7a[5], b[6], and c[7]). The different routes of assessment according to the class of the device are described in Article 52 and the Annexes IX, X, XI. In some cases manufacturers have some choice regarding the conformity assessment route.

For certain Class III and Class IIb devices there is a new clinical evaluation consultation procedure to be carried out by an independent expert panel, based on the clinical evaluation assessment report of the Notified Body (Article 54).

Annex I specifies the general safety and performance requirements, while Annexes II and III specify the makeup of the technical documentation.

The scope of the Quality Management System (Article 10 paragraph 9) now includes clinical evaluation and post-marketing clinical follow-up (PMCF). A clinical evaluation plan must precede the clinical evaluation itself (Annex XIV, Part A).

Common specifications defining additional requirements may be put in place for certain devices (Article 9).

Clinical requirements (Chapter VI)

The new Regulation reinforces the requirements for clinical evaluation (Article 61), introducing some of the biggest changes compared to the previous regime.

As under the Directives, it includes the collection of clinical data already available in the literature as well as the setting up of any necessary clinical investigations. The concept of equivalence with other devices for which clinical data already exists can still be used, but only in a limited number of situations, and the new rules are tighter (Article 61 paragraphs 4, 5, 6).

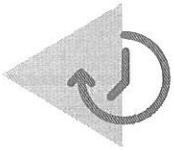
Article 62 and Annex XV set out the new and more precise requirements for clinical investigations. With only certain exceptions, implantable and Class III medical devices must now go through clinical investigations.

For all Class III devices, and for Class IIb devices intended to administer a medicinal product (or remove it from the body), the manufacturer has the option to consult a group of European experts to obtain an upstream review of its intended clinical development strategy (Article 61 paragraph 2).

5 "Devices placed on the market in sterile condition, to the aspects relating to establishing, securing and maintaining sterile conditions".
6 "Devices with a measuring function, to the aspects relating to the conformity of the devices with the metrological requirements".
7 "Reusable surgical instruments, to the aspects relating to the reuse of the device, in particular cleaning, disinfection, sterilization, maintenance and functional testing and the related instructions for use".

Summary of safety and clinical performance (Article 32)

For Class III and implantable devices, manufacturers shall draw up a summary of their safety and clinical performance in a form that intended users (and patients, if relevant) can understand. This summary will form part of the technical documentation sent to the Notified Body.



Timing your transition to the new Regulation

As a manufacturer, the timing of your transition to the MDR is up to you.

From 26 May 2020, all new certificates will have to be delivered according to the Regulation. The certificates delivered under the Directives can be valid until their date of validity for a maximum of four years (27 May 2024[8] at the latest). However, in the latter case, the requirements of the new Regulation relating to post-market surveillance, market surveillance, vigilance, and the registration of economic operators and devices shall apply from the Date of Application (Article 120 paragraph 3).

Class I devices (other than those that have a valid certificate under the Directive) will have to conform to the new Regulation from 26 May 2020.

Class I (except sterile devices, devices with a measuring function and reusable surgical instruments) and Class IIa might be easiest to start with. Classes IIb and III will be more challenging because of the more stringent requirements for clinical data.

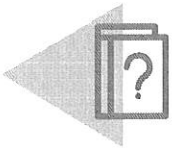
As a manufacturer, you can start now by making sure that:

1. all your products are classified appropriately;
2. all product documentation and evidence of compliance will be available in a timely fashion and conforms with the MDR; and
3. you have the necessary systems in place to handle clinical evaluation, quality management, post-market surveillance, and liability for defective devices.

More information

For more information on any of the above topics, please refer to the Medical Devices section on the DG GROW website.

https://ec.europa.eu/growth/sectors/medical-devices_en



Frequently asked questions

Below you can find an extract from the FAQs of the Competent Authorities for Medical Devices. For a complete list, see:

https://www.camd-europe.eu/regulatory/available-now-mdr-ivdr-transitional-faqs/

When does the Medical Devices Regulation (MDR) apply?

The MDR (EU) 2017/745 will apply from 26 May 2020 – the "Date of Application" (DoA).

Some provisions of the MDR will come into force earlier (e.g. regarding Notified Bodies and the Medical Device Coordination Group). Some will apply later (e.g. regarding UDI labelling).

When do the existing Directive cease to apply?

In general, Directives 90/385/EEC and 93/42/EEC will be repealed on 26 May 2020 (the DoA). However, there are some exceptions, such as:

- for the continued marketing of devices that comply with the Directives (see below); and
- to serve as a backup in case EUDAMED is not fully functional by the DoA.

What is the applicable legislation up to 26 May 2020?

Until the Date of Application, the laws and regulations adopted by Member States in accordance with the Directives will continue to apply. However, there are some exceptions.

Is it possible to place devices on the market that are compliant with the MDR prior to the DoA?

Yes, you may certainly place MDR-compliant devices on the market before the end of the transitional period. This applies to devices in all risk classes, and includes, for example, custom-made devices, systems and procedure packs.

However, devices subject to the "clinical evaluation consultation procedure", which covers certain devices in Classes IIb and III, may not be placed on the market before the Medical Device Coordination Group (MDCG) and the expert panels have been established.

Depending on the risk class of the device, conformity assessment may involve an appropriate Notified Body. This requirement may create further delays before such devices can be marketed due to the delays in the availability of appropriate Notified Bodies for all technologies.

8 There are some exceptions described in Article 120 paragraph 2

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As a manufacturer, which obligations of the Regulation do I need to fulfil in order to place compliant devices on the market before the DoA?

You should meet as many obligations as possible, bearing in mind that the complete MDR infrastructure, including EUDAMED, may not be fully functional before the Date of Application.

Both the device and the manufacturer must comply with the MDR. You should assess the conformity of your device – a process that may require the involvement of a Notified Body. Other important points include:

- Clinical evaluation
- Risk management
- Quality Management System (QMS)
- Post-market surveillance
- Technical documentation and other reports
- Liability for defective devices.

Until EUDAMED is fully operational, some parts of the Directives will have to substitute for the corresponding requirements of the Regulation. These include the registration of devices and economic operators.

A person responsible for regulatory compliance needs to be available but not necessarily registered until EUDAMED is operational.

Do certificates issued by Notified Bodies under the existing Directives remain valid after the DoA?

Yes, AIMDD/MDD certificates will generally remain valid until their indicated expiry dates. This applies to all the certificates commonly issued by Notified Bodies, including the EC Design-Examination Certificates, Certificates of Conformity, EC Type Examination Certificates, the EC Certificate Full Quality Assurance System, and the EC Certificate Production Quality Assurance.

However, all certificates issued after 25 May 2017 will be void at the latest by 27 May 2024. After this date there will be no more valid AIMDD/MDD certificates.

Is it possible to have valid MDR and AIMDD/MDD certificates in parallel until 27 May 2024?

Yes.

Can manufacturers still place on the market/put into service Directive-compliant devices after the end of the transition period?

Yes, under certain conditions there will be an option to continue placing on the market/putting into service devices that comply with the Directives until their existing certificates expire. This may avoid the immediate need for a new certificate under the MDR.

To use this option, all the existing certificates will have to be valid (including, for example, the QMS), the purpose and nature of the device must not change, and you must follow the new MDR rules for registration, surveillance and vigilance.

What is the "sell-off" provision about?

The "sell-off" provision is intended to limit the time during which devices that are compliant with the Directives and have already been placed on the market may be made available.

Any devices that are still within the supply chain and that have not reached their final user as being ready for use, for example a hospital, on 27 May 2025 are no longer marketable and must be withdrawn.

Once a Directive-compliant device has been made available to the final user by the deadline, the further making available of this device is not subject to/covered by the Regulation.

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