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The Medical Devices Regulation (EU) 2017/745 (MDR) finally enters into application – Are you ready?

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The Medical Devices Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices ('MDR') will finally enter into application on **26 May 2021**. The initial date of entry into application of the MDR was 26 May 2020, but it was eventually deferred by one year in accordance with Regulation (EU) 2020/561 of the European Parliament and of the Council of 23 April 2020 amending Regulation (EU) 2017/745 on medical devices, following the medical device industry's calls for postponement, to avoid potential market disruption and taking into account the COVID-19 outbreak and the associated public health crisis.

The MDR repeals the Medical Devices Directive 93/42/EEC ('MDD') and the Active Implantable Devices Directive 90/385/EEC ('AIMDD').

The date of entry into application of the In Vitro Medical Devices Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 ('IVDR') remains the same, namely, 26 May **2022**.

KEY CHANGES

Regulatory Scope

The regulatory scope of the MDR is more expansive than that of the previous regulatory regime and covers products that do not have an intended medical purpose (Annex XVI), including but not limited to:

- Non-corrective contact lenses;
- Aesthetic implants;
- Dermal fillings;
- Equipment such as lasers used for tattoo or hair removal, or skin treatment;
- Equipment intended for brain stimulation that applies electrical current or magnetic or electromagnetic fields.

The regulatory scope of the MDR also includes nanomaterials, medical devices manufactured by non-viable tissues or cells of human origin, as well as products specifically intended for the cleaning, disinfection, and sterilization of devices.

Classification

Classification rules under the MDR will mostly remain the same. The MDR, however, creates a slightly different regulatory landscape compared to that of the MDD by introducing changes in the classification of certain types of medical devices.

These changes include -but are not limited to- the following:

- A new sub-category of Class I medical devices is introduced, namely that of Class Ir medical devices (reusable surgical instruments) for which the involvement of a notified body is required. It should be noted that reusable surgical instruments were considered as general Class I medical devices under the MDD (Annex IX, Section 2.2, Rule 6);
- Stricter classification rules apply to medical devices software (MDSW) pursuant to Rule 11 of the MDR. As a result many types of MDSW that were categorized as general Class I (low risk) under the previous regulatory regime, will now be considered as Class IIa , Class IIb or even Class III medical devices depending on their intended use;
- Stricter classification rules apply to medical devices that are composed of substances or of combination of substances that are intended to be introduced into the human body via a body orifice or applied to the skin none of which be considered as Class I under the new regime (Rule 21).

Transitional Provisions

- Pursuant to Art. 120 par. 3 of the MDR:

- Class I medical devices, for which the declaration of conformity was drawn up prior to 26 May 2021, and for which the conformity assessment procedure pursuant to the MDR requires the involvement of a notified body (due to reclassification); or
- which have a valid certificate that was issued in accordance with the MDD/AIMDD,

may be placed on the market or put into service until 26 May 2024, provided that from 26 May 2021 they continue to comply with the previous regulatory regime (MDD, AIMDD), and provided there are no significant changes in their design and intended purpose.

However, the requirements of the MDR relating to post-market surveillance, market surveillance, vigilance, as well as registration of economic operators and medical devices shall apply in place of the corresponding requirements provided in the previous regulatory regimes.

- Pursuant to Art. 120 par. 4 of the MDR:

Medical devices lawfully placed on the market pursuant to the MDD/AIMDD prior to 26 May 2021, and medical devices placed on the market on or after 26 May 2021 pursuant to paragraph 3 of Art. 120, may continue to be made available on the market or put into service until 26 May 2025.

It should be noted that general Class I medical devices, namely, medical devices that are not sterile (Class Is) and/or do not have a measuring function (Class Im) are not eligible for any grace period and must be MDR compliant by 26 May 2021.

EUDAMED

Article 33 of the MDR establishes a European Database of Medical Devices (EUDAMED). Its purpose is to strengthen market surveillance and transparency by monitoring the safety and performance of medical devices and in vitro medical devices under the MDR and the IVDR. EUDAMED will contain data related to the medical devices themselves, as well as data concerning the economic operators (manufacturers, authorized representatives, and importers) associated with these devices. As regards distributors, Member States may maintain or introduce national provisions on registration, which have been made available on their territory.

In light of the fact that not all modules of EUDAMED will be operational before 26 May 2022[1], the Medical Devices Cooperation Group (MDCG) recommends that economic operators refer to the national provisions of Member States establishing product registration schemes.

As regards Greece, manufacturers and authorized representatives having their registered seat in Greece are encouraged by the National Organization for Medicines (EOF) to register with EOF's medical devices registry until 25 May 2022[2]. Interested parties may submit an amendment application for registration with EOF's electronic medical devices registry, where they shall post a declaration of conformity in accordance with Article 19 and Annex IV of the MDR. In case that the last renewal of the party's registration has taken place less than five years ago, no new fee needs to be paid.

UDI system

The MDR introduces an EU identification system for medical devices based on a Unique Device Identifier (UDI). The purpose of the UDI system is to facilitate the traceability of

[1]EUDAMED's "actor registration module", the first of six EUDAMED's modules has been available since 1 December 2020. The module on UDI/device registration (second module) and the module on Certificates and Notified Bodies (third module) will become available in September 2021 according to the European Commission.

[2] EOF's announcement of 17 March 2021.

medical devices and to allow monitoring by competent authorities.

A UDI is comprised of a UDI device identifier (UDI-DI), which is specific to a manufacturer and a device, and a UDI production identifier (UDI-PI), which identifies the unit of the device's production. The UDI system is connected to EUDAMED.

Economic operators have an obligation to assign a UDI to their products by 26 May 2021 at the latest.

Roles of Economic Operators

The roles of authorized representatives, importers and distributors are more enhanced as compared to the previous regime, which underlines the MDR's lifecycle approach to safety.

This is reflected in the following:

- Authorized representatives are jointly liable with manufacturers for defective products and must terminate the contract with a manufacturer that does not comply with the requirements of Article 10 of the MDR;
- Importers and distributors must verify the devices' compliance with the MDR and their obligations are, for the first time, clearly specified.

MDR Compliance Checklist

By 26 May 2021 manufacturers must comply with the obligations that derive from the MDR. Indicatively, they must:

- Have a Quality Management System in place in accordance with Annex IX of the MDR;
- Conduct clinical evaluation pursuant to Chapter VI of the MDR, meet MDR requirements related to market surveillance, post-market surveillance, and vigilance pursuant to Chapter VII of the MDR;
- Assign a UDI to their products;
- Follow labelling and packaging requirements (these will apply gradually from 26 May 2021).

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