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Implementation of the Medical Devices Regulation (EU) 2017/745 (MDR)

By Irene Kyriakides | January 21, 2020

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The Medical Devices Regulation (EU) 2017/745 (MDR) will soon become applicable and the medical devices companies, distributors and representatives should be prepared as that time has arrived. Its application date is set on 26 May 2020, despite the Industry's calls for postponement, following a three year transitional period from its entry into force on 25 May 2017. The aim of the present is to outline a couple of specific modified points: The criminal order (*"ποινική διαταγή"*):

- The MDR incorporates the two previous regulatory schemes (MDD and AIMD) in one;
- The certificates of medical devices obtained after the entry into force of the MDR (25 May 2017), under MDD or AIMDD, have a duration of no more than five years and will become void on 27 May 2024 at the latest;
- The liability of the MD companies' authorized representatives in case of no compliance is now extended and their obligations, provided up to this day by the European Commission's Blue Guide are now strictly regulated;
- The UDI system of identification and traceability of medical devices, which the manufacturers are required to place on the label or package of each medical device in order to achieve more safety and transparency, is introduced. However, it should be noted that the UDI's implementation depends on the MD classification;
- The original classification provided by the MDD remains unchanged with minor exceptions. However, some new definitions and terms are now provided by virtue of MDR and some products and devices that were not covered under MDD (e.g. particularly aesthetic products) are now governed by the regulatory scope.

Additionally, on December 2019 the Medical Device Coordination Group (MDCG) issued guidance notes for manufacturers of Class I Medial Devices to clarify the provisions of the MDR that will be applicable from May 2020.

The MDCG distinguished between two different conformity procedures depending on the classification of Class I Medical Devices. Hence, depending on whether the medical device is of Class Im (Devices with a measuring function), Class Is (Devices placed into the market in sterile condition) and Class Ir (Reusable Devices) the conformity procedure differs from the conformity procedure of the

medical devices of the General Class I category.

The manufacturers of all types of Class I devices should:

- Ensure that the medical devices meet the general safety and performance requirements of Annex I of Regulation (EU) 2017/745, adopting a continuous risk management system that will allow them to identify and evaluate the risks that each medical device might have or may have in the future;
- Comply with the technical documentation requirements of Annex II of Regulation (EU) 2017/745, conducting a clinical evaluation, and the technical documentation on post-market surveillance of Annex III of Regulation (EU) 2017/745.

Additionally, the manufacturers of Medical Devices of Class Im, Is, Ir have to conform to Chapters I and III of Annex IX and Part A of Annex XI, hence to establish, maintain and assess a quality management system with the involvement of a Notified Body. The latter's involvement varies depending on the type of Class I, namely:

- in case of Im devices, the Notified Body's involvement should concern the compliance of the devices with the metrological requirements
- in case of Is devices, the Notified Body's involvement should secure and maintain the sterile conditions
- in case of Ir devices, the Notified Body's involvement should relate to the reuse of the devices and in particular to the related methods of cleaning, disinfection, sterilization, maintenance, functional testing and the instructions for use.

It should be noted that the Guidance Notes clarified that manufacturers are not obliged to provide along with their medical devices instructions for use. However, the MDCG highlighted the obligation of manufacturers of Class Ir devices to issue instructions on cleaning and sterilization, establishing an exception to the general rule of no instructions for use.

By completing the above stages and by fulfilling all the requirements of the Regulation (EU) 2017/745, the medical devices of either Class I or Class Im, Is, Ir obtain EU Declaration of Conformity and CE mark. In conclusion, it should be noted, that Greece is in the process of issuing a Ministerial Decision that would align the national regulatory framework on the MDR provisions.

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