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Regulation (EU) 2017/745: new provisions for manufacturing and supply of medical devices

On May 25th, 2017, the new **Regulation (EU) 2017/745** on medical devices entered into force, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009, and repealing Directives 90/385/EEC and 93/42/EEC.

Although the new provisions will enter into force on **May 26th, 2020** (subject to the transitional provisions under Article 120 of the Regulation), companies operating in the medical devices business may decide to comply with most of the new provisions as of now.

The Regulation focuses, first of all, on the harmonization of the legislative framework governing medical devices, providing rules that (i) harmonize assessment procedures of medical products implemented by Member States and (ii) settle interpretative doubts arisen under the previous directives. Secondly, the Regulation aims to:

- ensure the free movement of medical devices for human use and their accessories on the European market;
- update provisions regulating the placing and use of these products within the European Union (EU);
- increase the safety of patients and users introducing stricter procedures to assess the conformity of products when they are placed on the market and even after their marketing.

The scope of the Regulation (art. 2.1) includes any type of implantable **medical device**, i.e. "*any instrument, apparatus, appliance, software, implant, reagent, material or other article intended by the manufacturer to be used, alone or in combination, for human beings for one or more of the following specific medical purposes:*

a) diagnosis, prevention, monitoring, prediction, prognosis, treatment or alleviation of disease" or other disabilities, and

b) *"investigation, replacement or modification of the anatomy or of a physiological or pathological process or state",* the main function of which is not exercised by pharmacological, immunological or metabolic means, but may be supported by such means.

Therefore, bandages, hip prostheses, syringes and pacemakers are all products that fall within the definition of *medical devices*. Moreover, the Regulation regulates:

i. clinical investigations concerning medical devices (and their accessories) conducted within the European Union; and
ii. products that do not have a medical purpose, such as coloured contact lenses and devices used for liposuction.

As provided by the previous legislation, the Regulation classifies the medical devices in relation to (i) their intended use and (ii) their risks. The **risk classes** (classes I, IIa, IIb and III set forth in Annex VIII of the Regulation) will be updated on the basis of the new technical documentation.

In particular, stricter clinical requirements and constant controls on processes may be provided for class III devices and so-called "implantable" devices (for example, invasive medical devices containing dangerous substances that may be classified as carcinogenic, mutagenic or toxic for reproduction, or that may interfere with the endocrine system).

Furthermore, the Regulation establishes that the manufacturers of medical devices shall provide patients with an implanted device with an implant card reporting some specific information such as:

- name, serial number, batch number, unique device identifier (UDI) and information concerning the manufacturer;
- warnings, precautions or measures to be taken in relation to external factors, medical examinations or environmental conditions; and
- information regarding the expected useful life of the device and any necessary follow-up.

Manufacturers of medical devices shall ensure high-quality management systems, stringent **safety controls** on manufactured devices, and security measures proportionated to the devices' class of risk, the type of device and the size of the company. In particular, manufacturers shall:

- ensure financial coverage in relation to their potential liability;
- appoint at least one person responsible for ensuring devices' compliance with legal requirements;
- plan, carry out and document an appropriate clinical evaluation similar to the one required for medicines;
- implement monitoring systems of devices after the placement on the market, through an evaluation made under real conditions of use (so-called *post-market clinical follow-up* - **PMCF**); it follows, therefore, that if the PMCF plan is not provided in relation to a particular medical device, the manufacturer is required to justify this omission.

The Regulation sets out measures to ensure the flow of data concerning the production of medical devices, through:

i. the introduction of a unique *device identification system* (**UDI**) for the registration and traceability of devices and manufacturers, importers and authorised representatives, in order to ensure promptly corrective actions if problems arise;
ii. the creation of a centralised database (*European database on medical devices* - **Eudamed**), conceived to process any information concerning medical devices circulating in the European Union and to make them available to Member States, businesses, patients, healthcare professionals and citizens.

In order to fully implement the EU guidelines and principles, each Member State must establish an "*authority responsible for notified bodies*" that are in charge of setting up and carrying out the necessary procedures for the assessment, designation and notification of conformity assessment bodies and for the monitoring of notified bodies (Articles 35 to 50).

To this end, any notification sent to a notified body for the assessment of the device's compliance shall be fully re-assessed three years after the first notification and every four years thereafter. To achieve these aims, notified bodies:

- may carry out inspections of production premises;
- shall meet the same quality standards throughout the EU; and
- shall engage trained personnel with technical and scientific skills and experienced in clinical sector.

Once the notified bodies are appointed, each Member State shall provide the Commission and the other Member States with relevant information concerning the notified bodies. To ensure this flow of information a dedicated electronic database shall be managed by the Commission so-called "*NANDO*".

It is very likely that the new regulatory system may be implemented by a set of national and European guidelines, based on data and experiences provided by operators of the medical devices sector. At the same time, however, the initial application of such guidelines shall constantly be monitored to ensure compliance.

Finally, some special provisions could enable the participation of small and medium companies in tenders for the supply of medical devices under clearer and more regulated procedures. An accurate analysis and review of tender specifications and supply contracts may be necessary to ensure compliance with the new provisions.

In conclusion, with Regulation (EU) 2017/745 the European Legislator intends: (i) to adapt the legislation on medical devices to the significant technological and scientific innovations; (ii) to provide and ensure compliance with assessment, safety and quality procedures of medical devices, in particular through provisions that enhance the circulation of data; and (iii) to raise end-users' level of information and protection.

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