THE SERVICE

REG. 2017/745 (MDR)

CE Marking of medical devices

SERVICE FINAL USERS

Medical Device Manufacturers

CONTEXT

Regulation 2017/745 establishes clear rules concerning all Medical Devices (MDs) to be placed in the market aiming to ensure, when MDs are used, maximum level of safety and protection of patients, users and other persons' health. Medical Devices are a wide range of products (instruments, apparatus, implants, substances, software or other) intended to be used in human beings or on human beings for diagnosis, prevention, monitoring or treatment, alleviation of or compensation for injuries or disabilities.

These devices are also used for investigation, replacement, or modification of the anatomy or of a physiological process or for the control of conception.

The medical device carries out its main action through means that are not pharmacological, immunological or metabolic, but whose function can possibly be assisted by these means (ancillary action). The product's intended use must be connotable as a medical purpose.

SERVICE

Certiquality, acting as Notified Body (no. 0546) for the Regulation 2017/745, performs all evaluations required to issue the CE Marking of Medical Devices in accordance with the product categories listed on the NANDO portal

CERTIFICATION PROCEDURE

- The Manufacturer submits a certification application to Certiquality (Notified Body);
- Certiquality checks the MD's technical documentation prepared by the Manufacturer;
- Certiquality audits the offices and production sites of the Manufacturer and, where needed, the premises of its critical suppliers;
- If the evaluations are successful, Certiquality issues the certificate for CE marking of suche MDs, with a period of validity of five years.
- During the Certificate Validity Period, Certiquality performs annual surveillance audits.

MARKET INTRODUCTION OF THE MEDICAL DEVICE

For the purposes of a correct market introduction of the Medical Device, it is the Manufacturer is responsible for:

- **Classifying the Medical Device. Classification is based on the intended use of the product.**

Regulation 2017/745 sets out that Medical Devices can be divided into four classes: I, IIa, IIb and III, depending on their complexity and the potential risk for patients, users or other persons.

- **Demonstrating the compliance of the Medical Device with Regulation (EU) 2017/745 Requirements.** To demonstrate the product conformity with the General Safety and Performance Requirements, the Manufacturer shall prepare appropriate technical and clinical documentation, describing the Medical Device and the related design, manufacture, marketing and post-market surveillance processes.
- **Guaranteeing and CE marking the Medical Device.** For Medical Devices having a class higher than I and for some aspects concerning class I devices (sterility, measuring function or reusability), the Manufacturer, before attesting product conformity, shall start an assessment of conformity procedure for the Device with the support of an independent third party, the Notified Body. For most Medical Device in Class I statement of conformity is carried out by the Manufacturer, by issuing the Declaration of Conformity.

MEDICAL DEVICE TECHNICAL DOCUMENTATION

The **Medical Device Technical documentation** consists of all the documents prepared by the Manufacturer, regardless of any partial or total outsourcing of the design and/or production, to demonstrate the compliance of the Medical Device with Regulation 2017/745 requirements. The technical documentation also include clinical evaluation to demonstrate the efficacy and safety of the medical device.

TRAINING

Certiquality provides courses that cover various subjects, such as:

- Regulation (EU) 2017/745 of 5 April 2017;
- Person responsible for the implementation of Regulation (EU) 2017/745;
- Risk management on the manufacturing process of medical devices in accordance with the ISO 14971 standard;
- Training on ISO 13485 standard (Quality System for Medical Devices);
- Design and validation of substance-based Medical Devices.