
# MD REGULATORY DIGEST

*FOCUS ON*

# DATE OF APPLICATION

In less than 1 year, the transitional period will come to its end and the Regulation (EU) 2017/745 will fully apply. Make sure you are ready on time!

## WHAT ARE THE CONSEQUENCES OF THE DOA?

As mentioned in Art. 123.2, the Regulation (EU) 2017/745 will fully apply on its Date of Application (DoA), set for **26 May 2020**. This will mark the end of the transitional period. From this date, **no new MDD certificate** will be issued.

MDD devices may continue to be placed on the market, provided:

- The related **MDD certificate** is still valid;
- There is **no significant changes**;
- The requirements related to PMS, market surveillance, vigilance, and registration of economic operators and of devices are **in accordance with the Regulation**.

## KEY STEPS TOWARDS MDR COMPLIANCE

3 steps are unavoidable for compliance with the Regulation.

### • Training

Of course, **training sessions** are crucial for a proper launch of the process of compliance with the MDR. A **good understanding** of the terms, but also the impacts of the Regulation, by all the stakeholders is essential to a smooth transition.

This first step may seem obvious, but should not be overlooked as it will leave you on a good footing.

### • Gap analysis

The training step lets you know where to go. The next thing to do is to know where you start, and to **evaluate the way to go** in order to define a path.

The best way is to make a **gap analysis** for each critical topic (e.g. Quality Management System, Technical Files, etc.).

This gap analysis shall include at least:

- The actions to be carried out,
- The people in charge,
- The deadline

for each topic.

### • Implementation

Once the path is defined, you can start the journey. But to know where to begin, you need to define a **hierarchy of tasks according to priorities**, so you can start by critical ones at first, and then implement the full plan.

Priority can be set according to different criteria, which are specific to each company.

## EFFECTIVENESS CHECK

The last thing to do is to check that all the actions you have implemented are effective and meet the specifications. Of course, **the process is not over until the requirements are met**.

## BREAKING NEWS

**TÜV SÜD (CE 0123)** became the second notified body designated to issue CE Mark certifications under Regulation (EU) 2017/745, following that of **BSI (CE 0086)**.

The designation covers all NBOG scope codes, but with 2 minor limitations:

• *Scope code MDN 1104*

Non-active soft tissue and other implants: Annexes X and XI without breast implants.

• *Scope code MDT 2013*

Devices which have undergone reprocessing: Only for medical devices that are foreseen by the manufacturer to undergo reprocessing.

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http://ec.europa.eu/growth/tools-databases/nando/index.cfm?fuseaction=notification.pdf&dir_id=34&ntf_id=295808