PATH TO REGULATORY COMPLIANCE

Health Portugal

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What is a medical device (MD)?

A medical device is any instrument, software, or material intended by the manufacturer for specific medical purposes in humans (see article 2(1) of Regulation (EU) 2017/745.

What is an in vitro diagnostic medical device (IVD)?

An IVD is any reagent, instrument, or software intended for the in vitro examination of human specimens to provide specific information (see article 2(2) of Regulation (EU) 2017/746).

RISK-BASED CLASSIFICATION

is essencial as many regulatory requirements are directly linked to the device's specific class.

Compliance is not a one-time process—it is expected throughout the entire product lifecycle, including design, development, testing and validation, manufacturing, labeling, marketing, user feedback, and post-market surveillance.

Understand your product

TIME AND COSTS

Work with timelines and align business expectations with process.

All devices, irrespective of the risk class, must comply with all obligations, which are often product specific, and bear a CE Mark to be sold in the EU.

Understand compliance

FIT BETWEEN COMPLIANCE AND PRACTICE

Adapt workflows to match with expectations.

Robust risk-based classification of the devices is essential as some of the requirements set out by the regulations are directly linked to device classification.

In Europe, conformity assessment is the process that demonstrates whether the requirements of the regulations relating to a device have been fulfilled, resulting in a CE marked product. In general terms, this usually involves the implementation of a quality management system and demonstration of conformity of devices against applicable requirements in the technical documentation.

Define a Regulatory Strategy

COMPLIANCE IS NOT A ONE-TIME PROCESS

It spans the entire products lifecycle.

PATH TO REGULATORY COMPLIANCE

RISK-BASED CLASSIFICATION DEFINE A REGULATORY PATHWAY STRATEGY

- What are the MDR/IVDR obligations?
- Do you need Quality Management System (QMS) certification?
- What are the general safety and performance requirements applicable to your device?
- What is the conformity assessment?
- Do you need to engage with a Notified body?

UNDERSTAND COMPLIANCE

- What regulations, laws and standards apply to your product?
- Regulatory authorities enforce these requirements to protect public health, patient safety and guarantee that MD perform as intended. For digital health and software as a medical device (MDSW), special attention should be given to some specific areas like cybersecurity, interoperability and software verification and validation.

UNDERSTAND YOUR PRODUCT

- Is it a medical device? How do you classify it?
- Understanding medical device classification is crucial for determining the applicable regulatory requirements. In general, medical devices are classified based on their intended use, risk level, and the duration of contact with the body. For digital health and MDSW, special attention should be given to the type of processing of data, type of data, level of automation and integration with other devices.

Medical Devices (MD)
Classes: I, IIa, IIb, III (lowest to highest risk).
Class I: low risk, no Notified Body unless sterile (Is), measuring (Im) or reusable surgical (Ir).
Classes IIa, IIb, III: always require a always require a Notified Body involvement.

In vitro Diagnostics (IVD)
Classes: A, B, C, D (from lowest to highest risk)
Classes B, C, and D require a Notified Body involvement.