Practical guidelines for marketing medical devices in Spain according to the AEMPS

2025 AEMPS Guide for marketing medical devices in Spain

Background

The medical device sector is governed by complex regulations that places obligations on both the products and the agents involved in their marketing. In Spain, Regulation (EU) 2017/745 (MDR) and Royal Decree 192/2023 coexist. Their application may raise questions due to their recent adoption and technical complexity, particularly during the current transitional period, in which devices regulated by the MDR coexist with others still regulated by the previous legal framework.

In April, the Spanish Agency for Medicines and Medical Devices (AEMPS) published its first Guide for the marketing of medical devices. This document serves as a highly practical tool, as it compiles and summarises the obligations that companies must fulfil when introducing or commercialising medical devices to the Spanish market.

After seeing how the Guide is applied in practice, we summarise below the main areas it clarifies, which are often the ones that tend to cause confusion in the sector.

Clinical research

To be marketed in the European Union, medical devices must bear the CE marking, except in the case of custom-made devices and those intended for clinical investigations.

According to the AEMPS Guide, clinical investigations are mandatory for implantable and Class III devices (with certain exceptions), as well as for other products when there is insufficient clinical data to demonstrate their safety and performance (Article 61 MDR).

In Spain, clinical investigations involving non-CE-marked products require prior authorisation from the AEMPS, a favourable opinion from the Committee on Ethics in Research with Medicinal Products (CEIm), and approval from the centre where the investigation is to be conducted.

Although the Guide does not explicitly address it, the same requirements apply when a CE-marked product is evaluated for a use outside the manufacturer's intended purpose. This is addressed by the AEMPS in their Instructions of 30 January 2023, which we analysed in a previous Capsulas.

AEMPS national registers of medical devices

Any company intending to market medical devices in Spain (excluding custom-made products), will have to register the device with the AEMPS Marketing Register, as set by Article 18 of Royal Decree 192/2023. However, this register is not yet operational, as it is linked to EUDAMED.

Until the Marketing Register becomes active, companies placing Class IIa, IIb or III devices on the Spanish market must notify the AEMPS through the CCPS application. For Class I or custom-made devices, notification is only required if the manufacturer, authorised representative, assembler or steriliser is established in Spain. In such cases, they must notify the AEMPS so that they can be

included in the Register of Responsible Entities for placing devices on the market.

Once the Marketing Register becomes operational, notification of all medical devices (except for custom-made devices) will be mandatory through this system. Custom-made devices will continue to be notified in Register of Responsible Entities for placing devices on the market.

Distribution and sale

A distributor is defined as any person or entity in the supply chain (other than the manufacturer or importer), who makes a product available on the market until it reaches the end user as a product ready for use.

Distributors and any person or entity established in Spain who intends to market medical devices, regardless of their classification, must notify the start of their activity in advance to the health authority of the autonomous region where their registered office is located (Article 23 of Royal Decree 192/2023). If they have warehouses in other regions, they must also notify the respective health authorities in those regions.

This obligation applies whether products are sold online or through physical retail outlets. When the notification is submitted, the authorities typically request information about the distribution channel. Additionally, physical establishments that sell products requiring individual adaptation must obtain authorisation from the autonomous region in which they are located and comply with the requirements outlined in Article 26 of Royal Decree 192/2023.

Pharmacies are exempt from this prior notification requirement, unless they market products that require individual adaptation. In such cases, they must comply with the same rules as other establishments.

The Guide is silent regarding distributors or persons or entities not established in Spain who intend to market medical devices. However, in practice, neither the AEMPS nor some regional health authorities currently require prior notification. Even so, it is advisable to monitor how this practice develops to stay ahead of any potential changes.

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