ASPHALION MedTech

Spanish Market - Additional National Procedures for Medical Devices (AEMPS)

ASPHALION
MedTech

Additional National Procedures of the AEMPS for Medical Devices

The Spanish Agency for Medicines and Medical Devices (AEMPS) is the governmental entity responsible for ensuring the quality, safety, efficacy, and accurate information of medicines and medical devices in Spain. As part of the Ministry of Health, the AEMPS ensures products are safe and effective, from the research phase to their final use.

agencia española de medicamentos y productos sanitarios

In this context, in Spain, economic operators that manufacture and/or market medical devices or perform related activities, must comply with both European requirements and national requirements established in the Royal Decree 192/2023. This article outlines the key requirements related to licenses, communication of the commercialization of medical devices, and distributor obligations.

Prior Operating License for Establishments

Manufacturers, groupers, sterilizers, and importers established in Spain need to apply for a prior operating license.

Licenses are granted by the AEMPS and are valid for a maximum of five years. The electronic application IPS (Instalaciones de Productos Sanitarios), is available for processing license applications, modifications, and renewals. Any modification to the license will require prior approval from the AEMPS.

Who Must Obtain the License?

- **Mass-produced medical devices manufacturers**
- **Manufacturers of complete products to third parties**
- **Reprocessing manufacturers**
- **Third-party sterilizers**

→ **Prior operating license for establishments for the manufacture, sterilization and reprocessing of medical devices**

- **Medical Device Grouper**
- **Importers**

→ **Prior operating license for import establishments and grouping of medical devices**

This requirement applies to all of the following types of products: Medical devices, in vitro diagnostic medical devices and their accessories, products listed in Annex XVI of Regulation (EU) 2017/745 (products without an intended medical purpose), and equipment and instruments used for permanent, semi-permanent makeup, or tattooing of the skin using invasive techniques.

For Custom-Made Medical Devices:

A license issued by AEMPS is required for:

- Manufacturers of custom-made medical devices in the autonomous cities of Ceuta and Melilla.
- Importers of custom-made medical devices.

>> Manufacturers of custom-made medical devices not located in Ceuta and Melilla need an operating license issued by their respective autonomous community.

The following companies or activities are not subject to licensing:

- ✕ Companies (except sterilizing entities) performing specific manufacturing stages for third parties without marketing the products under their own name.
- ✕ Companies whose sole activity is the distribution of medical devices.
- ✕ Laboratories controlling medical devices.

AEMPS National Registers of Medical Devices

In addition to obtaining a license for the aforementioned activities, any economic agent marketing or putting into service for the first time a medical device in Spain must notify the AEMPS. Depending on the product and operator, one or both of the available Spanish databases must be used for communication.

CCPS (Communication of Commercialization of Medical Devices):

This AEMPS application facilitates communications related to the commercialization and/or placing on the market of Class IIa, IIb, and III medical devices, as well as in vitro diagnostic devices. The CCPS database also enables users to modify, cancel, or consult submitted communication data.

Who Must Communicate?

CCPS

- Manufacturer
- Authorized representative
- Importer
- Distributor
- Grouper

- Marketing or putting into service for the first time in Spain.
- May be established in Spain or abroad.
- Must carry out the communication, regardless of whether another agent has communicated the same product.

- Class IIa, IIb, and III medical devices
- In vitro diagnostic medical devices of classes B, C, and D
- In vitro diagnostic medical devices from Lists A and B and for self-diagnosis

Communication is required regardless of whether the agent is established in Spain or abroad and even if another marketer has already communicated the same product. Direct retail points and pharmacies are exempt.

The registration and communication of medical devices involve a fee, as well as an annual maintenance fee for the communicated products' information.

> ***NOTE**: The AEMPS is currently developing a new Commercialisation Registry for medical devices, which will be integrated with the European EUDAMED database. Once this system becomes operational, all medical device notifications—regardless of class and excluding custom-made products—will be submitted through the new registry. The current CCPS application will be phased out.*

RPS (Register of Persons Responsible for Placing Medical Devices on the Market)

RPS is another application managed by the AEMPS, primarily used for Class I and custom-made medical devices, as well as for third-party sterilizers. Manufacturers established in Spain who place Class I or custom-made devices on the market are required to notify the AEMPS via RPS to be included in the corresponding database. This requirement also applies to authorized representatives, groupers, and sterilizers based in Spain. Importantly, submitting an RPS notification does not incur any fees.

ASPHALION MedTech

RPS

- Manufacturer
- Authorized representative
- Grouper
- Sterilizers*

- Place medical devices on the market.
- Established in Spain.

*Sterilizers of systems, sets, or equipment for medical or surgical procedures or sterilizers of CE-marked products intended to be sterilized before use and for which they are responsible for placing on the market.

- Class I medical devices
- Custom-made devices
- In vitro diagnostic medical devices

> ***NOTE**: RPS will remain operational and coexist with EUDAMED and the new Commercialization Registry for Medical Devices (when active) for the communication of custom-made medical devices.*

In certain cases, it is necessary to register the same product in both registries CCPS and RPS (**dual communications**):

- Marketers in Spain of in vitro diagnostic medical devices from Lists A, B, or for self-diagnosis according to the Directive and in vitro diagnostic medical devices of Class B, C, or D according to the Regulation.
- Groupers established in Spain and marketing their products in Spain, when including any component of the grouping of Classes IIa, IIb, or III. Different aspects are communicated, even if they refer to the same products.

National Requirements for Distributors

Distributors of medical devices in Spain must notify the start of their activity to the health authority of the corresponding autonomous community where the company's registered office is located. It is also necessary to notify the health authority of the community where the warehouse(s) are located if they are not in the same community.

Moreover, they must register in the CCPS (for applicable products) and, when launched, in the AEMPS Registry for the Commercialization of Medical Devices before starting their marketing activities. Pharmacies and other exclusive retail points are excluded.

Other Requirements for In Vitro Diagnostic Medical Devices (IVD) to consider:

There are some IVD reagents that may be used for military purposes and may be subject to additional requirements. In these cases, it is necessary to review whether reagents, toxins or other agents that may be considered **dual-use items** in Spain are included.

Dual-use items and technologies are subject to control and **require authorization in certain cases under Regulation (EU) 2021/821**. For the purposes of the Regulation, '**dual-use items**' means items, including software and technology, which can be used for both civil and military purposes, and includes items which can be used for the design, development, production or use of nuclear, chemical or biological weapons or their means of delivery, including all items which can be used for both non-explosive uses and assisting in any way in the manufacture of nuclear weapons or other nuclear explosive devices.

The list of dual-use items and technologies is specified in Annex I of Regulation. There are dual-use items or technologies that, although not identified in the Annex I list, are subject to control under the catch-all clause. This means that, if an exporter knows or has reason to suspect that the items to be exported are intended for purposes that may contribute, in whole or in part, to:

- Development of chemical, biological or nuclear weapons, missiles capable of delivering such weapons, or nuclear explosive devices.
- Military end use.
- Use as accessories or components of defense material, which has been exported without proper authorization.

In such cases, the exporter must inform the competent authority, which will decide whether the export should be subject to authorization. This system ensures that Spain complies with its international commitments on non-proliferation and control of sensitive products, as part of the international control regimes.

Conclusion

Complying with national regulations is the key to the successful marketing of medical devices in Spain. Systems such as **IPS, CCPS and RPS**, make it easier for companies to comply with Spanish requirements while ensuring the safety and efficacy of products reaching the Spanish market. Adherence to these procedures ensures that companies contribute to the protection of public health, while operating in accordance with current regulations.

ASPHALION
MedTech

WHY WORK WITH US?

ASPHALION's experts have delivered solutions to over 1,000 Pharmaceutical, Biotechnological and Medical Technology companies from more than 50+ countries in over 5,000 projects covering non-clinical and clinical development, CMC, dossier writing, regulatory procedures, vigilance, eSubmissions and data management for both medicinal products and medical devices.

Multidisciplinary team: clinical & regulatory affairs and quality assurance

Pragmatic approach to guide medtech developers

Experience with a wide variety of medical technologies

Flexible collaboration model for start-ups, SMEs and large companies

Optimization of Time to Market

ASPHALION
MedTech

Need help? Contact us!

www.asphalion.com

info@asphalion.com

+34 93 238 59 45

Author

Itxaso Beltrán de Guevara

Medical Device Officer