The AEMPS launches a new application for the communication of *in-house* manufacturing of medical products by hospitals

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- **The new computer application allows hospitals to report their *in-house* manufacturing activity to the AEMPS**
- **All hospitals that are currently manufacturing medical devices *in-house must make this communication.***

The Spanish Agency for Medicines and Medical Devices (AEMPS) has launched a **new computer application** for the electronic submission of the communication of the start of the manufacturing activity of medical devices in hospitals for their exclusive use in the hospital itself. Such manufacturing must have the purpose of satisfying the specific needs of the group of patients for whom the products are intended, which cannot be satisfied or cannot be satisfied with the appropriate level of performance, by another product with CE marking on the market. This activity is commonly known as *in-house* manufacturing of medical devices .

Regulation **(EU) 2017/745** of the European Parliament and of the Council of 5 April 2017 on medical devices regulates in its article 5.5. the requirements for the manufacture of medical devices *in-house* in healthcare centres.

Furthermore, **Royal Decree 192/2023** , of March 21, regulating medical devices, establishes in its article 9 the requirements and conditions for carrying out this activity in Spain. It should be noted that, according to the Royal Decree, this activity can only be carried out by hospitals and the manufacture of products of classes IIb, III, or implantable products is not permitted. On the other hand, the presentation of a communication prior to the start of the activity to the AEMPS is required. Likewise, hospitals must communicate through this means any modification in the activity or the communicated products.

It should be noted that this manufacturing does not apply to custom-made medical devices, which require a prior operating license for their manufacture by the Autonomous Community.

Hospitals will be able to access the application using a username and password. Each hospital must have a coordinator to request registration in the application. **Instructions** for accessing the application and submitting the communication can be found on the AEMPS **website .**