

Requirements for suppliers of Medical Devices

Dear supplier,

As a distributor of medical devices, we have certain legal obligations regarding the monitoring of the products we sell. To comply with these requirements, we need additional information about the medical devices you will be supplying to us.

1. Identification of Medical Devices

As a first step, we would like to know which of your products **are classified by you as medical devices**. For some items, it is not immediately clear whether the manufacturer actually places them on the market as medical devices.

2. Documentation to Be Provided

Once it is clear which products are offered as medical devices, our creation department will request you to upload the following documents/information to the digital product sheet via a datapool connected to the GDSN-GS1 network (such as MPM):

- **FAMHP (FAGG) Registration Certificate**

The certificate must state your FAMHP registration number, as well as the activities for which you are registered. You can download this document via the FAMHP portal under “My Activities”.

- **EU Declaration of Conformity:** In accordance with Annex IV of the MDR.

- **CE Certificate from a Notified Body**

Required in addition to the EU Declaration of Conformity for all medical devices, except those in Class I.

- **PDF of the labelling/packaging and instructions for use**

We must be able to see the full (unfolded) packaging in a PDF, image, screenshot, or similar format.

- **Shelf-life information and storage conditions**, if applicable.

3. Internal Quality Control

Our quality department will thoroughly review all provided information. This includes verifying the conformity of the packaging and ensuring that all mandatory statements and information are present as required by applicable legislation, **before** we offer the items **for sale**.

This way, we ensure together that the medical devices offered are compliant with European regulations, and that we can provide safe and compliant products to our consumers.

Thank you in advance for your cooperation.