# THE MDR JOURNEY

*NEWSLETTER No. 24 – April 2021*

*«Let's make transparency a standard requirement»*

## Subject: How should an incident with a device in an Article 22 Procedural Pack (PP, CPT) be managed?

### Request Notified Body involvement

Any natural or legal person who sterilizes systems or procedure packs referred to in paragraph 1 and intends to place them on the market shall, at their preference, apply one of the procedures set out in Annex IX or the procedure set out in Part A of Annex XI. **The application of those procedures and the notified body's involvement shall be limited to the procedure's aspects relating to ensuring sterility until the sterile packaging is opened or damaged.** The natural or legal person shall draw up a statement declaring that sterilization has been carried out following the manufacturer's instructions.

In the case of devices placed on the market in sterile conditions, the assembler (PPP) will apply the procedures set out in Chapters I and III of Annex IX or in Part A of Annex XI MDR. This requires the involvement of an NB.

PPPs can choose any NB designated according to the MDR for the relevant codes and corresponding types of devices as established by Regulation (EU) 2017/2185 (MDS 1005 - Devices in a sterile condition, MDS 1011 Devices in systems or procedure packs and MDT 2011 - Devices which require packaging, including labeling).

The list of designated NBs is available in the NANDO database at the following link: http://ec.europa.eu/growth/tools-databases/nando/

### Does the manufacturer manage this directly with the Competent Authority without going through the Procedure Pack Producer (PPP)?

The manufacturer is responsible for reporting all serious incidents and field safety corrective actions (FSCA) to the relevant CAs, according to Article 87 (1) of the MDR. After serious incident notification, the manufacturer is obliged to make investigations, according to Article 89, which will include a risk assessment of the incident. If needed, an FSCA will be implemented to reduce the risk associated with the device's use.

The manufacturer will involve the distributors of the device and, where applicable, the authorized representative and importers in the system to obtain the information needed from the market, especially for FSCA, and issued field safety notices (FSN) to ensure that required actions are followed and completed promptly.

The root cause of the incident may be with the manufacturer's device itself (manufacturer's responsibility), or with the PPP's assembled CPT, i.e., with its combination/configuration, processing/sterilization, etc. the components of the procedural pack (then the responsibility lies with the PPP).

Should the PPP have access to the relevant information, the PPP should actively monitor' EUDAMED vigilance entries related to utilized devices (once Eudamed is available).



It is recommended that there be a written agreement between the PPP and manufacturer who provides devices inclusion into a PP regarding how vigilance is managed. **The manufacturer should inform the PPP of vigilance cases and vice-versa.** As the PPP's name must appear on the PP, the complaint may be sent to the PPP directly by the customer and not to the components' manufacturer.

The Commission EU expects assemblers to have an appropriate and robust quality system to ensure the post-market surveillance (PMS) obligations, including vigilance reporting, of all manufacturers whose devices are included in their system and procedure pack (PP), can be fulfilled. This system should ensure effective communication of safety reports and other post-market information between assemblers and the component device manufacturers and identify the activities and responsibilities for the assembler and each of the manufacturers for the following key issues:

- Vigilance and complaint reporting
- Incident investigations
- Field safety corrective action (FSCA) implementation

Concerning PMS the assembler of a system or procedure pack should consider their declaration regarding mutual compatibility and the PMS and vigilance obligations of the component device manufacturers.

Regarding the declaration of mutual compatibility, it is expected that the assembler has a system to review experience gained from the use of his product. **For example, this would include procedures for conducting investigations to determine whether a reported incident occurred due to a compatibility issue between the component devices or whether it resulted from a problem with the individual CE-marked device.** Without having such a mechanism in place, the assembler might not be aware of issues that could affect his declaration's validity.

**Regarding the component device manufacturers' PMS obligations, the system or procedure pack's assembler should immediately notify the component device manufacturers of any incident involving their device. This is essential to ensure the component device manufacturers meet their obligations for vigilance reporting.**

Similarly, suppose an assembler is informed of a FSCA relating to a device contained within his system or procedure pack. In that case, they must ensure that the necessary actions are carried out effectively and efficiently for all of their products, including the affected devices, including the component devices in a system or procedure pack.

**This may require issuing his customer communication to ensure all affected users know the component device manufacturers' FSCA.**

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*This newsletter is part of our campaign to increase the sensitivity and the awareness of all our business partners, to bring more clarity around the MDR journey and challenges and opportunities around the MDR Art.22 "Systems and Procedure Packs."*

*We are already today all dependent on practical cooperation. For the MDR implementation, we require even closer collaboration to ensure we all can deliver safe supply to hospitals and patients in the future.*

*We are confident we'll continue to supply health care competently on customized surgical procedure sets and small kits.*

*Do you want to know more about specific topics? Do you have any questions or comments?*

*Write us* *MDR2020@stsmedicalgroup.com*

*The next MDR Newsletter will be issued in May. We wish everybody pleasant days.*

**Augusto Orsini**
CEO STS Medical Group

**Katarzyna Zofia Chrusciel**
Corporate Technical Director
Quality Management and Regulatory Affairs