THE MDR JOURNEY

***NEWSLETTER No. 6 – September** 2019*

«Let's make transparency a standard requirement»

Subject: MDR preparation of the STS Medical Group, Nr.6 September 2019

Dear Customer,

After holidays we are approaching the last part of the year. Most medical device manufacturers are still working intensively on the MDR preparation to make the journey successful.

In this release, we would like to outline some details to the Art. 12 MDD which will be Art. 22 under the MDR "Systems and Procedure Packs".

What is a Procedure Pack?

Procedure Packs in the sense of the MDR are units of different medical devices that are packed together for the convenience of the user. For a certain surgery always the same instruments, gloves, drapes, gowns or other medical devices may be required. One of the benefits of a procedure pack is that the medical devices do not need to be picked one by one before a surgery but can be picked at once.

What is the difference to a System?

A System is a medical device or a combination of medical devices that are used together to achieve an intended use. Like a tracheal tube, the breathing circuit and the resuscitator. None of these Medical devices can achieve the intended use to ventilate of the patient but together as a system, they do. To be part of a system it is not a determining factor to be sold together. It is enough that these medical devices are intended to be used together.

What can be the content of a Procedure Pack?

A procedure pack can consist of different medical devices and in-vitro diagnostic medical devices that bear a CE marking. The fact that now also in-vitro diagnostic medical devices can be packed in procedure packs is an additional positive aspect coming with the MDR. Furthermore it is now allowed to pack non-medical devices into the procedure packs if they "*are in conformity with legislation that applies to those products only where they are used within a medical procedure or their presence in the system or procedure pack is otherwise justified.*" A justification may be a box where small things are stored within the set or a container to store things prior to deposition. However, these non-medical devices must not have an intended use.

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What are the obligations for the manufacturer of a Procedure Pack?

1. *Mutual compatibility*

At first the manufacturer of such an procedure pack has to "*verify the mutual compatibility of the devices… in accordance with the manufacturers' instructions …*".

One point of the mutual compatibility is that all components of the procedure packs correspond to the intended use of the procedure pack. As an example, a procedure pack is intended for an invasive surgery and there are swabs included to soak the blood during the surgery. The swabs that are used are used inside the body. In this case, the swab's intended use must also cover a usage inside the body.

Another point is the physical compatibility of the interfaces of products inside the procedure pack. An example may be two medical devices that must be put together via a connector. Here the manufacturer has to ensure that the devices in the procedure pack have suitable connectors.

Additional restrictions of manufacturers or limits of use of a medical device have to be considered. Maybe the manufacturer of a medical device restricts the use of its medical device in a way that it cannot be combined with certain other medical devices.

2. *Information accompanied need to be passed through to the intended user*

The manufacturer of a procedure pack has "…*supplied relevant information to users incorporating the information to be supplied by the manufacturers of the devices or other products which have been put together;*".

It is in the responsibility of a manufacturer of a procedure pack to ensure that all relevant information, which is on the labels or the instructions for use for a component of the pack, is provided together with the pack to the user. All symbols on the labels of components, all restrictions, intended use etc. everything that may be important for the usage of the components (medical devices) must be provided.

3. Monitoring, verification and validation

The manufacturer has to ensure that *"…the activity of combining devices and, if applicable, other products as a system or procedure pack was subject to appropriate methods of internal monitoring, verification and validation."*

The manufacturer of a procedure pack has to ensure like every manufacturer for a medical device that the manufacturing steps are appropriate to ensure that the procedure pack is safe and effective when it will be used by the user. This comprises in-process controls, and verification and validation activities.

Thinking of the repacking of the medical devices in one big procedure pack and the subsequent sterilization. This of course requires the manufacturer of a procedure pack to perform a sterilization validation.

In addition this packaging needs to be robust enough that it can be shipped to the sterilization site and later on to the customer (Transport Validation). And of course the sterile barrier - and this is what the packaging is about - must be still sufficient and undamaged after the shelf life of the procedure pack. To ensure the shelf life the manufacturer must conduct verification activities in conjunction with accelerated aging and real-time aging.

Technical Documentation

Although we talk about a procedure pack consisting of a number of CE-marked medical devices the manufacturer of such a procedure pack is required to keep up a extensive technical documentation.

Another part is the "General Safety and Performance Requirements" Checklist of the MDR. In this Checklist evidence regarding the requirements of the MDR have to be provided. As an example this checklist contains requirements regarding the development, presence of CMR (**C**arcinogenic, **M**utagenic, or toxic for **R**eproduction) or endocrine-disrupting substances, the conduction of Risk Assessments, how to label a medical device, mandatory information to be provided to the user, etc. This list contains 23 items with many sub items and has an extent of 14 pages in the MDR.

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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 an effective cooperation. For the MDR implementation, we require even a closer collaboration in order to ensure we all can deliver safe supply to hospitals and patients in the future.

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

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 October.

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