Newsletter 2019/02

The new EN ISO 17664:2017 for Processing of health care products – Are your products affected?

What is the EN ISO 17664:2017 about?

The new EN ISO 17664:2017 standard defines the requirements for the **information to be provided** by the medical device manufacturer for the **processing of a medical device in the instructions for use**. Processing means cleaning followed by disinfection and/or sterilization to ensure that the device is safe and effective for its intended use.

Who is affected?

Manufacturers of medical devices that are intended for invasive or other direct or indirect patient contact. In case that the products are **intended to be processed** by the user or a third party to be made ready for use the instructions for use have to comply with EN ISO 17664:2017. This includes the following medical devices:

- **Reusable medical devices** and
- **Single-use medical devices** that are **sold non-sterile but are intended to be used in a clean, disinfected and/or sterile state** and therefore have to be processed prior to their use.
- Following are examples of products which are not affected: Non-critical medical devices with no direct patient contact; textile devices used in patient systems or surgical clothing; or medical devices specified by the manufacturer for single-use only and supplied ready for use.

How are medical devices classified as (non-/semi-) critical?

According to Spaulding's classification medical devices are grouped according to their intended use:

Non-critical items: Contact with intact skin only or devices not intended for direct patient contact (e.g. blood pressure cuffs, bedpans, crutches)
Semi-critical items: Contact with mucous membranes or non-intact skin (e.g. anesthesia equipment, respiratory equipment)
Critical items: Medical devices that normally enter sterile parts of the human body (e.g. surgical instruments, implants, invasive medical devices)

What is new in the EN ISO 17664 version of 2017 (compared to the 2004 version)?

- More detailed description required for complete processing process (cleaning, disinfection and/or sterilization)
- Now also includes single use devices that require cleaning/sterilization before use
- Now also valid for medical devices that are invasive or in direct/indirect contact with patient
- New requirements for the validation of the processes that have to be included in the instruction for use

Background

To minimize the risks of transmission of infectious agents or other adverse effects it is pivotal to have available and follow detailed processing instructions. The basic step for processing of medical devices is cleaning. In case of reusable medical devices, based on the geometry of the medical device, contaminations in- or outside of the medical device can impair the subsequent disinfection and/or sterilization and even the correct function. In addition, also single-use medical devices can require a cleaning step before further processing. The influence of

other factors (e.g. storage) might also affect the safety or effectiveness of a medical device. In this case the manufacturer can help the users by providing instructions for inspections and testing.
The manufacturer has the responsibility to ensure that the medical devices are designed in a way which allows effective processing. To prove the effectiveness of processing (cleaning, disinfection, and/or sterilization) these processes shall be validated.

Content

The standard EN ISO 17664:2017 does not provide defined processing instructions. It rather specifies requirements to assist manufacturers in providing detailed processing instructions for the following steps (if applicable):

- Initial treatment at the point of use
- Preparation before cleaning
- Cleaning
- Disinfection
- Drying
- Inspection and maintenance
- Packaging
- Sterilization
- Storage
- Transportation

Validation of the processes

The medical device manufacturer shall **validate each procedure** that is specified in the instructions for use. The validation must provide objective evidence that the mentioned procedures are suitable for processing of the medical device. In case that manufacturers supply a number of different medical devices with the same characteristics, validation studies for product families can be performed. If this approach is chosen, the medical device manufacturers shall demonstrate the correspondence between the various medical devices and the validation studies must apply to the worst case attribute(s) of the product family, e.g. the medical device with the most complicated geometry or devices consisting of several materials. We recommend contacting an accredited test laboratory (e.g. ISO 17025) for preparing the test reports. **Be aware that the competent authorities often request the validation reports!**

Risk analysis

A risk analysis shall be performed to determine the content and details of the information in the instructions for use. The risk management must be in compliance with ISO 14971.

Information to be provided by Medical Device Manufacturer

For preparing the information to be provided by the manufacturer the **nature** of the medical device and its **intended use** have to be taken into account. For the final procedure (either disinfection or sterilization) the medical device manufacturer shall establish the **validated method(s)** for reducing the risk of transmission of infectious agents to the level appropriate for the intended use of the medical device. Medical device manufacturers must specify in their processing instructions specific techniques and accessories that will enable the processor to provide a medical device suitable for its intended use. Manufacturers should consider available national and international standards and guidelines; the need for special training, and if the required equipment is generally available to the processor. For each processing step at least one method should be validated. The method should be typical for the market. In case the processing will limit the service life of the medical device, then the manufacturer has to inform about limitations and restrictions, e.g. a limited number of processing cycles or incompatibility with substances or processing conditions.

Cleaning of medical devices is always an important topic. It is a must that **at least one automated cleaning method has to be validated**. An exception is only possible if the medical device will not withstand automated cleaning with a washer-disinfector. In this case the manufacturer shall provide a statement that warns the user and have a validated method for the manual cleaning.

Also for disinfection at least one validated automated disinfection method with a washer-disinfector shall be specified. If automated disinfection is not possible the

manufacturer have to provide alerts to user and a validated method for manual disinfection. If sterilization is the terminal process then at least one validated method has to be listed in the instructions for use.

The EN ISO 17664:2017 is not harmonized until now (https://ec.europa.eu/growth/single-market/european-standards/harmonised-standards/medical-devices_en) but has been adopted for Germany as DIN EN ISO 17664:2018. This new standard is relevant for all medical device manufacturers that have registered or will register their products in Germany.

We strongly recommend reviewing this norm and evaluating if it is also relevant for your medical devices.
(https://www.iso.org/standard/62952.html)

CAUTION: Under the MDR a notified body has to be involved for conformity assessment in case of reusable surgical instruments (even for class I). This covers the aspects relating to the reuse of the device, in particular cleaning, disinfection, sterilization, maintenance and functional testing and the related instructions for use!

For more detailed information, please do not hesitate to contact us: ecrep@medneteurope.com

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