Recommendations by the quality task group (107)

# Information to be provided by the medical device manufacturer for the processing of medical devices

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Recent amendments to EN ISO 17664

## Introduction

**THE INFORMATION PROVIDED BY** the manufacturer serves as the basis for processing

The information provided by the manufacturer serves as **THE BASIS FOR PROCESSING** each and every medical device (MD) and makes stringent demands on the organizational skills of a Reprocessing Unit for Medical Devices (RUMED) [1] with regard to the practicability and implementation of such processing measures.

The revision of EN ISO 17664:2017 is an opportune moment to examine the changes made to the standard as well as their implications for everyday practice. This present publication also updates Recommendation 46 of the Quality Task Group.

Compared with EN ISO 17664:2004-07 [2] changes were made which are listed on page 2 of the standard (see Item "Amendments"):

- The title of the standard has been expanded to include the entire medical device processing process and all medical devices (previously limited to the sterilization process and resterilizable medical devices)
- The scope of the standard as reflected by the change of title includes the entire processing process (cleaning, disinfection and/or sterilization) and is no longer limited to reusable medical devices subject to terminal sterilization; the standard applies to invasive or other medical devices coming into direct or indirect contact with patients.

**THE MEDICAL DEVICE MANUFACTURER MUST PROVIDE INFORMATION PURSUANT** to EN ISO 17664 for considerably more medical devices now.

Compared with previously, the medical device manufacturer must provide information **PURSUANT TO EN ISO 17664** for considerably more medical devices. These include, in addition to the "resterilizable medical devices" listed hitherto, all MDs [3] coming into direct or indirect contact with the patient, e.g. stethoscopes, flexible endoscopes, lamp holders, breathing equipment, tourniquets. Further instructions can also be found on this on page 2 and 3 (EN ISO 17664):

- Definitions adapted to existing standards and following terms newly introduced: "medical device", "reusable medical device", "single-use medical device", "processing", "service life", "packaging system", "protective packaging", "sterile barrier system" ", "sterility assurance level", "terminal process" and "verification"
- The requirements for validation of processes specified in the information to be provided by the medical device manufacturer (see Section 4) and requirements for risk analysis (Section 5) have resulted in a fundamental revision of the previous Sections 5 (Validation) and 6 (Risk analysis); the formation of medical device groups is now regulated by a standard

The idea of medical device groups was already addressed in Recommendation 105 *(Risk assessment and release of new medical devices before investment and new procurement)* of the Quality Task Group but now using the term *group formation*: "It may also be useful to form MD groups in terms of their suitability for the available process(s) so as to categorize the reprocessing problems associated with particular MDs. That task is made easier if equivalence to available, already evaluated, MDs can be established".

The specified risk analysis must concord with EN ISO 14971 "Medical devices – application of risk management to medical devices" (EN ISO 17664, Item 5). The following aspects are of relevance for the medical device manufacturer:

- Nature and design of the medical device
- Composition of the contaminants on the medical device
- Intended purpose

- Service life of the medical device
- Foreseeable application errors and misuse
- User training
- Equipment required for processing
- Accessories and consumables required for processing
- Medical device servicing required
- Postmarketing information
- Limitation of the number of reprocessing cycles
- Warning instructions required

It is likely that **INFORMATION PERTAINING EXCLUSIVELY TO MANUAL PROCESSING** will be omitted in the future since now only one process need be described. From page 3 of EN ISO 17664 the following can be inferred:

- The requirements for the information to be provided by the medical device manufacturer (see Section 6) have been fundamentally revised (formerly Section 3), inter alia, the requirements for the transportation have been newly incorporated; specification of one cleaning and disinfection process is adequate but preference should be given to automated processes (if necessary including manual precleaning); less information may be provided on cleaning and disinfection processes while making reference to washer-disinfectors (WDs) as per standard series EN ISO 15883; the same applies for conventional sterilization processes

**INFORMATION PERTAINING EXCLUSIVELY** to manual processing will be omitted in the future.

In this regard **DEMONSTRATION OF THE EQUIVALENCE OF MANUAL PROCESSING METHODS** to automated processes is also cumbersome. For that reason, too, it is likely that descriptions of manual processes will be omitted since such tests are very onerous.

The medical device manufacturer is obligated to provide objective proof that the specified processing methods assure the desired outcome. This involves confirmation that the specific medical device is clean, disinfected and/or sterile when used if it has been processed as instructed. In other words the MD manufacturer must validate each process included in the information supplied (EN ISO 17664, Item 4.1).

**DEMONSTRATION OF THE EQUIVALENCE** of manual processing methods to automated processes is very cumbersome.

### How do I recognize non-compliant instructions?

Basic instructions regarding the processing methods (validation parameters), e.g. temperature, time, water quality but also generic information such as the use of process chemicals (expressed in general terms such as e.g. neutral, mildly alkaline, alkaline) should be listed (see EN ISO 17664, Item 6.2.2):

- Details of the process steps
- Description of equipment and/or accessories
- Specification of process parameters and their tolerances

Annex A and B of EN ISO 17664 contain guidance for compilation of manufacturer instructions. The tables featured there can also be used as guidance for evaluation of the manufacturer's instructions.

Will be continued in Issue no. 4/2018

### References and abbreviations

1. RUMED – Reprocessing Unit for Medical Devices
2. EN ISO 17664:2017 – Processing of health care products - Information to be provided by the medical device manufacturer for the processing of medical devices
3. MD – Medical device

| Sample checklist, requirements taken from the standard | |
|---|---|
| **Process** | **Possible instructions** |
| Initial treatment at the point of use | ▪ If applicable, tests (e.g. leaks)<br>▪ If applicable, cleaning steps (e.g. flush lumen)<br>▪ If applicable, transportation (protective caps, etc.)<br>▪ If applicable, maximum waiting time until processing in the RUMED |
| Preparation before cleaning | ▪ If applicable, dismantling<br>▪ If applicable, tests<br>▪ If applicable, precleaning (e.g. ultrasound)<br>▪ If applicable, accessories and implements required (brushes, etc.) |
| Cleaning | ▪ If applicable, reference to standards<br>▪ If applicable, loading pattern (e.g. racks)<br>▪ If applicable, connections<br>▪ If applicable, accessories<br>▪ Process chemicals, if applicable connections<br>▪ Process parameters (temperature limit value(s), concentration, contact time, water quality, process steps)<br>▪ If applicable, rinse methods |
| Disinfection | ▪ Appropriate disinfection processes<br>▪ Process parameters (see above) |
| Drying | ▪ If applicable, special requirements<br>▪ if applicable, techniques<br>▪ If applicable, process parameters |
| Inspection and maintenance | ▪ If applicable, process qualification and alignment<br>▪ if applicable, lubrication/care<br>▪ if applicable, assembly<br>▪ if applicable, accessories and implements required |
| Sterilization | ▪ If applicable, reference to standards<br>▪ If applicable, specific loading pattern,<br>▪ If applicable, accessories<br>▪ Specific process parameters (pressure, time or temperature limit value) |
| Storage | ▪ If applicable, specific restrictions on storage time or storage conditions (e.g. maximum temperature, humidity) |
| Transportation | ▪ if applicable special protective measures |