Newsletter 2019/02

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

针对医疗产品清洗、消毒和灭菌（处理）的新欧盟标准 EN ISO 17664：2017 – 您的产品是否受到影响？

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 which 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 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.

EN ISO 17664：2017 是关于什么的？

新的 EN ISO 17664：2017 标准规定了医疗器械制造商**在使用说明书**中**提供处理医疗器械操作方法的要求**。此处的“**处理**”意即清洗，消毒和（或）灭菌，以确保该医疗器械安全有效地达到其预期用途。

谁受到影响？

生产侵入性医疗器械或其他直接/间接接触患者医疗器械的制造商。若产品须由使用者或第三方**做清洗消毒灭菌处理才能使用**，则其使用说明书必须符合 EN ISO 17664：2017。 这包括以下医疗器械：

- **可重复使用的医疗器械**和
- **一次性使用的医疗器械，但出售时是非灭菌状态，而且需要在清洁的，已消毒和/或无菌状态下使用**，因此必须在使用前进行处理。
- 以下是不受影响的产品示例：不直接接触患者的非危险医疗器械；用于患者系统或手术服的纺织品；或即时可用的一次性使用医疗器械。

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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)

什么是（非/半）危险医疗器械?

根据 Spaulding 分类法，医疗器械按其预期用途被划分为：

非危险器械：仅与完整皮肤接触或不与患者直接接触的器械（例如血压袖带，便盆，拐杖）
半危险器械：接触粘膜或非完整皮肤（例如麻醉器械，呼吸器械）
危险器械：通常进入人体无菌部位的医疗器械（例如手术器械，植入物，侵入性医疗器械）

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 which 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

EN ISO 17664 的 2017 版有哪些新增内容（与 2004 版相比）？

- 要求完整的处理方法（清洗，消毒和/或灭菌）做更多详细描述说明
- 现在还涵盖了在使用前需要清洗/灭菌的一次性使用器械，
- 现在仍适用于侵入性或直接/间接接触患者的医疗器械
- 新提出要求对说明书里的处理方法进行有效性验证。

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

背景

为了最大限度地降低传染性病原体传播的风险或其他不良影响，最重要的是要获得并遵守详细的处理说明。处理医疗器械的基本步骤是清洗。基于可重复使用的医疗器械的构型，其内部或外部的污染可能影响随后的消毒和/或灭菌，甚至影响该器械的正常功能。此外，一次性医疗器械也可能需要在进一步处理之前进行清洗步骤。其他因素（例如存储）也可能影响医疗器械的安全性或有效性。在这种情况下，制造商可以提供检查和测试方法以帮助用户。

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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.

制造商有责任确保医疗器械的设计使该器械能得到有效处理。为了证明处理（清洗，消毒和/或灭菌）的有效性，厂商还应验证这些过程。

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

内容

EN ISO 17664：2017 不提供标准的处理方法而是提出明确要求， 以帮助制造商按以下步骤的提供详细处理说明（如果适用）：

- 使用时的初始操作
- 清洗前的准备工作
- 清洗
- 消毒
- 干燥
- 检查和维护
- 包装
- 灭菌
- 存储
- 运输

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.
Be aware that the competent authorities often request the validation reports!

处理方法的验证

医疗器械制造商应**验证使用说明中指定的每个步骤**。该验证必须提供客观证据，证明这些处理步骤适用于该医疗器械。如果制造商供应多个具有相同特征的医疗器械，则可以对该产品系列进行验证。如果厂商采取系列产品一起验证的方法，医疗器械制造商应证明该系列中各产品之间的对应关系，该验证必须适用于产品系列中最坏的情况，例如：具有最复杂形状的医疗器械或由多种材料组成的器械。**请注意，主管当局经常要求提供验证报告！**

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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 has to provide alerts to user

风险分析

应进行风险分析，以确定使用说明书中信息的内容和细节。风险管理必须符合 ISO 14971。

医疗器械制造商提供的信息

为了按法规要求提供信息，制造商必须考虑医疗器械的**性质及其预期用途**。对于最终程序（消毒或灭菌），医疗器械制造商应提供**被验证有效**的处理方法，以降低传染性病原体传播的风险，使其达到适合该器械预期用途的水平。医疗器械制造商必须在其处理说明中提供适合该器械预期用途的特定技术和条件。制造商还应考虑国内和国际标准和准则;是否需要特殊培训；是否容易获得所需的处理设备。对于每个处理步骤，应该验证至少一种方法。该方法应该是市场的典型方法。如果该处理方法将影响医疗器械的使用寿命，则制造商必须告知该影响和限制，例如，产品处理的次数限制或某些物质或加工条件的限制。

医疗器械的清洗始终是一个重要的主题。厂商**至少必须验证一种自动化清洗方法**。只有在医疗器械无法承受清洗消毒器的自动清洗时才可以例外。在这种情况下，制造商应提供声明警告用户的，并至少提供手动清洗方法及其验证。

同样，厂商也至少要提供一种经验证有效的使用清洗消毒机的自动化消毒方法。如果产品不能用于自动化消毒，制造商就必须提供替代方法及其

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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.

验证。
如果灭菌是最终过程，则必须在使用说明中列出至少一种经过验证的灭菌方法。

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.

EN ISO 17664：2017 至今尚未成为协调标准（https://ec.europa.eu/growth/single-market/european-standards/harmonised-standards/medical-devices_en），
但已被德国采用为 DIN EN ISO 17664：2018，此新标准适用于已经或将要在德国注册其产品的所有医疗器械制造商。

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

我们强烈建议您查看此规范并评估其是否与您的医疗器械相关。
(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, to the aspects relating to the reuse of the device, in particular cleaning, disinfection, sterilization, maintenance and functional testing and the related instructions for use!

注意：MDR 实施后必须由认证机构对可重复使用的手术器械的合格评定，将涉及器械重复使用的方面，特别是清洗，消毒，灭菌，维护和功能测试以及相关说明书！）

For more detailed information, please do not hesitate to contact us!
若需要任何详细信息，随时欢迎联络我们

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