



ISO 11607 – How to translate into action Sterile container systems

Emar Heid, Aesculap





ISO 11607 – How to translate into action Sterile container systems

- ISO 11607, **part 1** specifies the basic attributes required of materials and pre-formed systems intended for use in packaging systems for terminally sterilized medical devices.
- ISO 11607, **part 1** also specifies general requirements for all packaging materials.



important for the **manufacturer** of materials and packaging systems to provide safe materials and systems

- Manufactures of sterile containers may demonstrate compliance with this ISO 11607, part 1 by using requirements and test methods described in EN 868, part 8 : Re-usable sterilization containers for steam sterilizers conforming to EN 285 – requirements and test methods



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ZERTIFIKAT ♦ CERTIFICATE ♦ CERTIFICADO ♦ CERTIFICADO ♦ CERTIFICATE ♦ 認証証書



CERTIFICATE

The Certification Body
of TÜV Management Service GmbH
certifies that

AESCULAP AG & CO.KG
Am Aesculap Platz, D-78532 Tuttlingen
Carl-Braun-Strasse 1, D-34212 Melsungen

has established and applies
a Quality Management System for

**Development, Production and Distribution of Implants, Instruments,
Containers, Devices, Suture Material, Tissue Adhesive and Procedure Kits**

- Surgical, diagnostic and dental instruments
- Joint Implants (e.g. hip, knee, shoulder)
- Spinal Implants
- Implants for Otolaryngology
- Neurosurgical Vascular Implants
- Motor systems
- Sterilization containers and accessories
- High frequency surgery devices
- Endoscopy systems
- Navigation systems
- Surgical suction pumps
- Hot air sterilizers and autoclaves
- Veterinary instrumentation and animal clippers
- Hair cutting machines
- Surgical suture material and special suture-sets
- Implants for replacement of connective tissue
- Tissue adhesive
- Vascular prostheses and accessories
- Local haemostatic
- Peripheral stent
- and other surgical accessories

An audit was performed, Report No. **70062209**
Proof has been furnished that the requirements
according to

ISO 9001: 2000
are fulfilled. The certificate is valid until **2008-05-31**
Certificate Registration No. **12 100 21724 TMS**





Munich, 2005-05-31



TÜV Management Service GmbH · TÜV SÜD Gruppe · Zertifizierungsstelle · Ridlerstrasse 65 · 80339 München · Germany


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CERTIFICATE
No. Q1N 05 05 10066 151

Holder of Certificate: **AESCULAP AG & CO. KG**
Am Aesculap-Platz
78532 Tuttlingen
Germany

Facility(ies):
AESCULAP AG & CO. KG
Am Aesculap-Platz, 78532 Tuttlingen, Germany
AESCULAP AG & CO. KG
Carl-Braun-Str. 1, 34212 Melsungen, Germany

Certification Mark:



Scope of Certificate: **Design and Development, production and
distribution of implants, instruments,
containers, devices, suture material, tissue
adhesives and procedure kits
(see attachment)**



Applied Standard(s): EN ISO 13485:2003
Medical Devices - Quality Management Systems -
Requirements for regulatory purposes

The Certification Body of TÜV PRODUCT SERVICE GMBH certifies that the company mentioned
above has established and is maintaining a quality system which meets the requirements of the
listed standards. See also notes overleaf.

Report No.: 70094073

Valid until: 2008-05-31

Date: 2005-05-18 

TÜV Product Service GmbH
TÜV SÜD Gruppe · Zertifizierungsstelle
Ridlerstr. 65 · 80339 München
Germany

Akkreditiert durch
Zentralstelle der Länder
für Gesamthochschul-
berufsprüfung
und Hochschulprüfungen
ZLG-ZG-999.98.12-46

The activities described in ISO 11607, part 1 shall be carried out within a formal quality system



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General requirements for reusable sterile containers:

Essential facts and their implication for your daily work with sterile containers

- Sterile containers belong to the group of **preformed sterile barrier systems** (pouches, bags and reusable containers) and are defined as „**rigid sterile barrier systems designed to be repeatedly used.**“



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Specific requirements for reusable containers according to ISO 11607, **part 1**

- Every container shall be equipped with a tamper-evident system to provide a clear indication when the closure integrity has been compromised.





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Sterile container systems

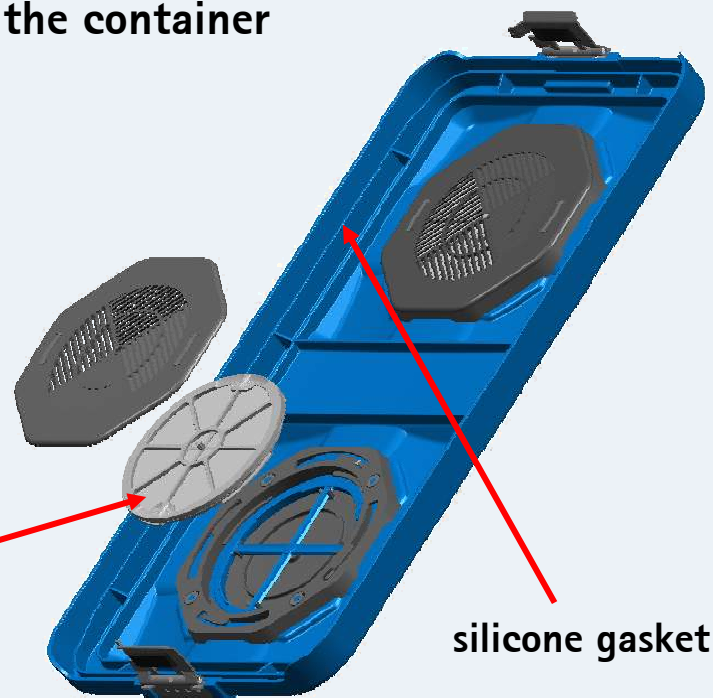
Specific requirements for reusable containers according to ISO 11607, **part 1**

- The sterilization agent port and the closure shall provide a barrier to micro organisms during transport and storage of the container

There is no universally accepted method of demonstrating microbial barrier properties.

Suitable methods are listed in the standard

Filter system

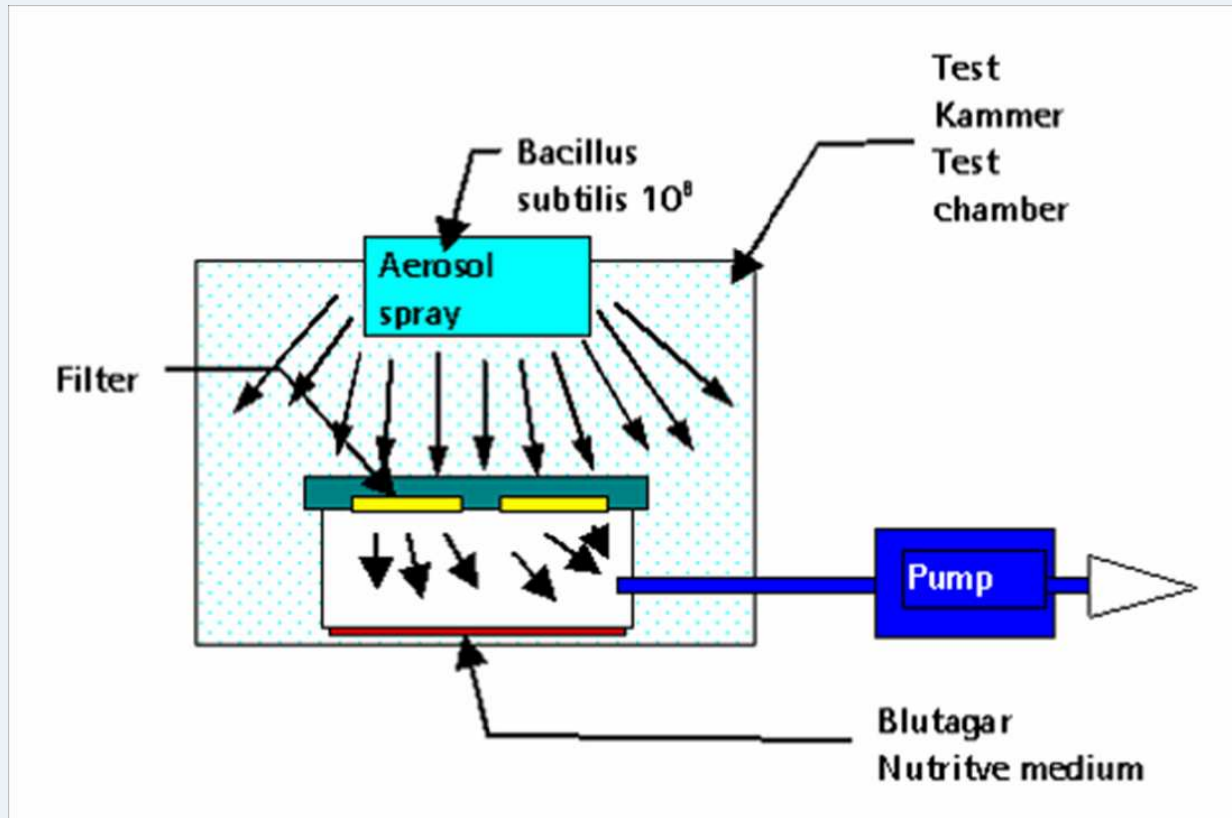


silicone gasket



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Commonly used performance testing for reusable sterile containers:



Junghannß, Gabele, et al.: Hygienic-Microbiological and Technical Testing of Sterile Container Systems. *Zentr.Steril.* 1999,



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Specific requirements for reusable containers according to ISO 11607, **part 1**

- The container shall be constructed to **facilitate inspection** of all essential parts.
- **Acceptance criterias** shall be established for inspection prior to each use

**Visual inspection is the most common procedure,
there could be also other acceptable methods**



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Aesculap Sterile Technology

Sterile container system
Edition 07/2006



- 📖 Instructions for use/Technical description
Sterile container system
- 📖 Gebrauchsanweisung/Technische Beschreibung
Sterilcontainer-System
- 📖 Mode d'emploi/Description technique
Système de conteneurs de stérilisation
- 📖 Instrucciones de manejo/Descripción técnica
Sistema de contenedores estériles
- 📖 Istruzioni per l'uso/Descrizione tecnica
Sterile container system

4.2 Function checks

- Prior to each use, carry out a visual inspection for damage and correct functioning of all components of the sterile container:
 - Metal parts not deformed
 - Aluminum lid not warped
 - Seals intact
 - Plastic parts not cracked
 - Permanent filter intact
 - Lock functions properly (engages)
- Use sterile containers only if they are in mint condition. Replace any damaged components immediately with original spare parts or have the affected components repaired.

**Follow the Instructions for Use
(IFU)**



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Sterile container systems

Specific requirements for reusable containers according to ISO 11607, **part 1**

- Individual components of the same type of containers must be **interchangeable** or otherwise designed that the components cannot be mixed and interchanged.
- Do not mix parts of containers from different brand and manufacturers



one type of bottom, fully interchangeable lids



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- Cleaning and maintenance information shall be specified by the manufacturer

- Refer to manufacturers information for use
- Aesculap Extranet: Database Care and Maintenance including all Aesculap products

Material-specific requirements for the cleaning and disinfection of sterile containers

	Disposal container, stainless steel	Standard container, anodized aluminum	PrimeLine container, plastic
Ultrasound treatment in manual and mechanical processing	√	√	√
Cleaning/ Disinfecting agent*	acid, pH-neutral, alkaline	pH-neutral, mildly alkaline	pH-neutral, mildly alkaline
Thermal disinfection with fully desalinated water, 5 min, at 93 °C	√	√	√
Mechanical drying with hot air at up to 120 °C	√	√	√
<p>* Mildly alkaline cleaning/disinfecting may cause surface changes discoloration of the aluminum lids (fading, staining). Such changes do not affect the functionality of the product. For colored aluminum lids use, if possible, a process involving a neutral cleaning and disinfecting agent and fully desalinated water.</p>			



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Specific requirements for reusable containers according to ISO 11607, **part 1**

Maintenance of sterile containers

According to the EN 868, part 8:

- Serviceable life of a container should **not be less than 500 cycles**.
- Serviceable life of the silicone gaskets should **not be less than 100 cycles**.

If the service life shall be demonstrated by **accelerated ageing procedures**, the ageing procedure according to Annex G of EN 868, part 8 shall be used

Aesculap did a validation for the serviceable life of our containers based on this ageing test for 5000 cycles.



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Specific requirements for reusable containers according to ISO 11607, **part 1**

- Compatibility with the sterilization process = refer to manufacturers IFU

2.1 Intended use

The Aesculap sterile container system is intended for use as sterile packaging for instruments and textiles due for steam sterilization through a validated steam sterilization process (e. g. in a sterilizer complying with EN 285/ANSI/AAMI/ISO 11134-1993, ANSI/AAMI ST46-1993 and validated according to EN 554/ISO 13683).

After sterilization, the sterile materials are stored in the sterile container until they are used.

Note

Please contact your Aesculap representative if your Aesculap sterile containers are to be used in any other steam sterilization process.



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ISO 11607, **part 2**: Validation requirements for forming, sealing and assembly processes : practical impacts

- Sterile containers are sterile barrier systems
- Sterile containers can be used without additional protective packaging
- Sterile containers are rigid sterile barrier systems and can be used and are most commonly used without wrapping the instrument tray inside.





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ISO 11607, **part 2**: Validation requirements for forming, sealing and assembly processes : **practical impacts**

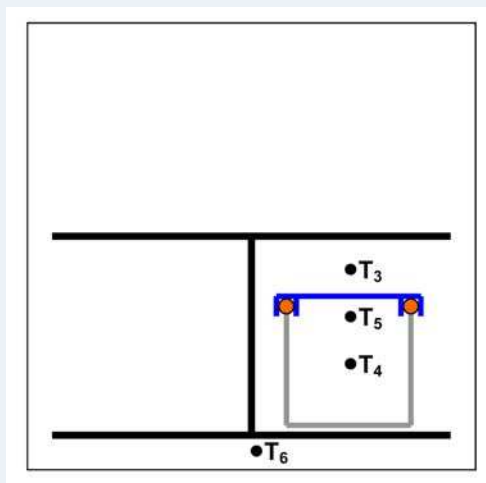
- Sterile containers are already **preformed**: the user just need to put in his instrument baskets and close the lid.
- However there are still points which needs to be observed in order to achieve the expected result of the entire packaging and sterilization process:
a safe and sterile set of instruments.
- It is recommended to install within the quality management system of the sterile supply department **Standard Operating Procedures** for the necessary working steps and controls.



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ISO 11607, **part 2**: Validation requirements for forming, sealing and assembly processes : practical impacts

- Processes shall be revalidated if changes are made to the packaging materials.



Permanent filter cartridges for testing with thermocouples are provided by Aesculap



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ISO 11607, **part 2**: Validation requirements for forming, sealing and assembly processes : **practical impacts**

After the cleaning process a **visual control** of the **essential parts** of the container should be implemented:

- Barrier system in place or intact, disposable filters replaced, no visible damages
- Filter retention system engaged if applicable
- No visible damages of the lid and the upper edge of the bottom part
- Silicone gasket in place and without any visible damages
- Closing latches/system without visible damages
- Closing latches/system engage and not loose



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ISO 11607, **part 2**: Validation requirements for forming, sealing and assembly processes : **practical impacts**

Forming process:

- According to EN 285 and EN 868, part 8 the total weight of the instrument load should not exceed 10 kg inside a full-size container
- After closing the lid the container will be sealed with a tamper evident system.
- A labelling system is used to provide all necessary information for the documentation and follow up of the individual container.





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ISO 11607, **part 2**: Validation requirements for forming, sealing and assembly processes : practical impacts



- For sterilization, transport and on stock rigid containers can be stacked



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ISO 11607, part 2: Validation requirements for forming, sealing and assembly processes : **practical impacts**

- The loss of sterile package integrity is usually regarded as event related than time related.
- To be able to demonstrate that the sterile barrier system maintains integrity over time Aesculap performed **event related shelf life testing over the period of 360 days.**

The responsibility however for the handling and storage conditions of sterile goods rests with the user.



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Don't be scared, just do it !!!