Practical experience in implementing the validation of sterile barrier systems according to ISO 11607-2:2020 at CSSD in Germany

DGSV
Deutsche Gesellschaft für Sterilgutversorgung e.V.

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Agenda

- Laws and standards according to the ISO, EN and German Rules
- Why validation?
- Overview in packaging of sterile medical products
- Who must validate? Who is allowed to validate?
- Validation Plan
- IQ
- OQ
- PQ
- Validation Report
- Routine Controls
- Experiences/ Lessons Learned/ THM

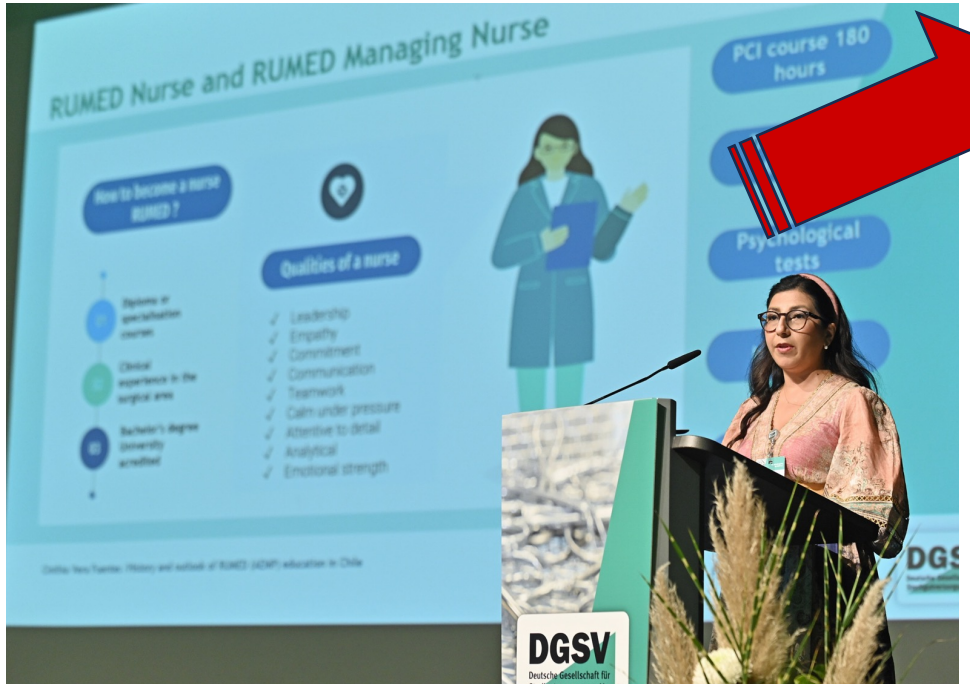
Introduction

- The last revision of the IN EN ISO 11607-2 was in 2020
  - according to the new European harmonised Medical Device Regulation (MDR) which was activated in 2017
  - MDR Annex I Chapter II/11.5 says *"Products labelled 'sterile' shall be processed, manufactured, packaged and sterilized using appropriate validated processes."*
  - this results in a legal requirement for the validation of packaging processes

- The German Guideline is a practical approach set the ISO-Standards in CSSD
- The German Medical Devices operator ordinance forms the framework for the obligation to validate

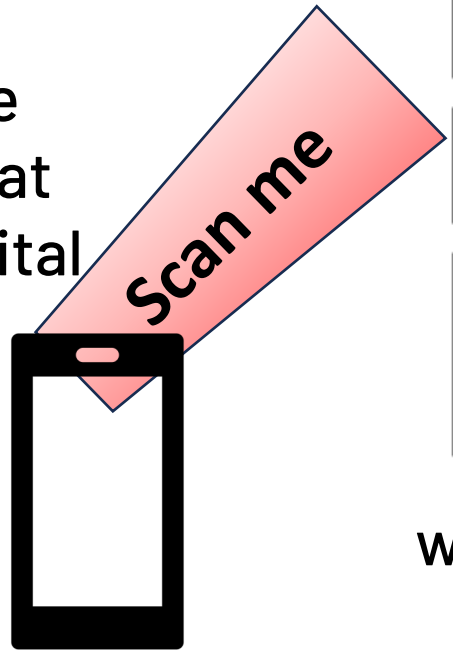
Why this Lecture/ Why this Topic?

- The last autumn the German Board of the DGSV®e.V. invited Mrs. Cinthia Vera Fuentes to their annual Kongress to give a Lecture about the Chilean education system for reprocessing
- As a re-invitation the German Board asked, how they can support important Topics in South-America as best



Why this Lecture/ Why this Topic?

- To make this lecture “ready to use” in your countries, we translated the Guideline in cooperation with Mrs. Westermann from MHP-Verlag and Mr. Pilasi in English and Spanish language.
- You can get the printed brochure at the booths of our industrial Supporters, that gave the financial support and also digital
  - B.Braun Aesculap
  - Dr. Weigert
  - Entrhal Medical
  - Hawo
  - KLS Martin
  - Miele/Steelco/Belimed
  - MMM
  - Richard Wolf
  - VP Stericlin



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Why validation?

- To make sure:
  - that process and production are running comparable in every cycle
  - that processes comply with the specified specifications and regulatory requirements from laws, standards and regulations
  - that Patients are safe in usage of the reprocessed medical devices

Principles of Validation?

- Installation Qualification (IQ), Operational Qualification (OQ), Performance Qualification (PQ)
- all processes must be validated
- “Worst-Case” as a based principle
- Validation of the process, not of the device

Overview in packing Materials/ Structure of the Guideline

- There are 3 common Categories for packaging of Medical Devices as a sterile-barrier-system (SBS)

Chapter A:

Validation of the sealing process

"Filling and sealing pouches and reels"

Chapter B:

Validation of the soft packaging

"Filling, folding, wrapping and closing sterilization sheets"

Chapter C:

Validation of the packaging process with sterilization-containers

"Filling and closing of reusable containers"

Source: A,B: VP Stericlin, Feuchtwangen; C: B.Braun Aesculap, Tuttlingen

Who must Validate?

The **EN ISO 11607-2** standard applies to industry, healthcare facilities and any other facility where medical devices are packaged and sterilized.
So according to definition also: **Hospitals and medical and dental practices**

Who is allowed to validate?

Persons who have verifiable knowledge in the areas of quality management and validation in the processing of medical devices

According to the Medical Devices Operator Ordinance, the supervisory authority is authorised to have this knowledge proven

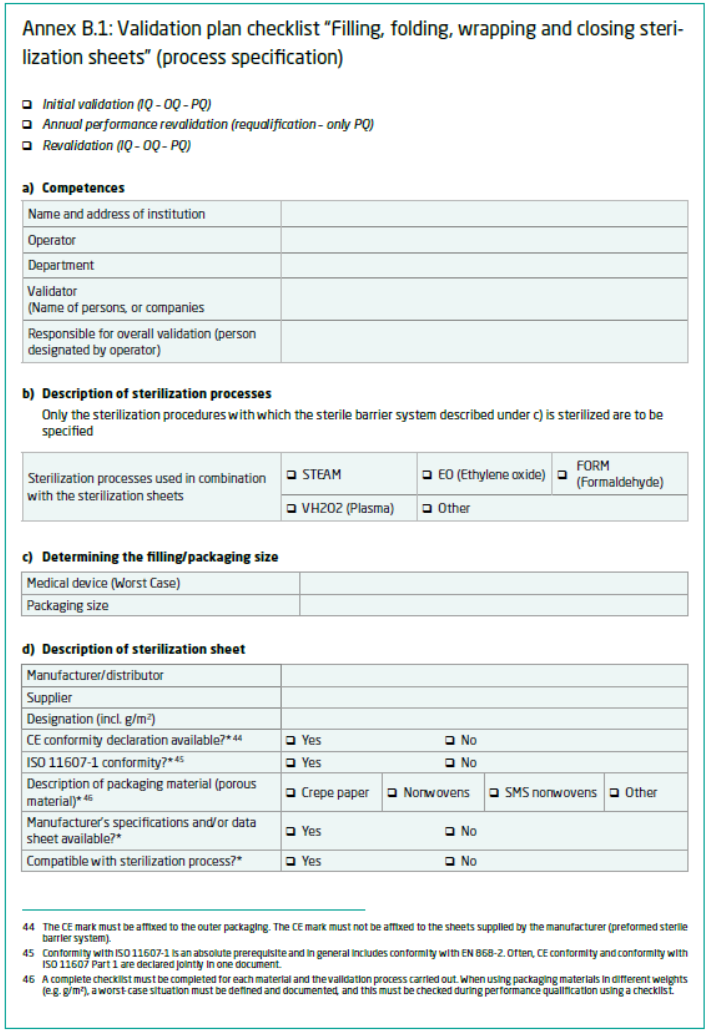
Validation Plan

- Type of validation
  - (First) validation (IQ / OQ / PQ)
  - Renewed Performance Assessment (PQ) (also called "annual revalidation")
  - Validation when changing devices/ Validation when changing materials
  - General re-validation like (first) validation
- Responsibilities
- Description of the devices
  - packaging materials or sterile barrier systems
  - packaging processes
  - separate closure systems for sheets
  - Papers of conformity → (Challenge for every SPD-Manager)
- Designation of sterilization procedures

→ **Create ONE validation plan for EACH type of packaging and manufacturer**

Supplementary documents for the validation plan

- training documentation
- installation evidence
- acceptance confirmations
- Proof of manufacturer
  - IFU
  - Declaration of Conformity
  - Certificates et cetera
- Standard Operating Procedures
- …



Annex B.1: Validation plan checklist "Filling, folding, wrapping and closing sterilization sheets" (process specification)

- ❑ *Initial validation (IQ - OQ - PQ)*
- ❑ *Annual performance revalidation (requalification - only PQ)*
- ❑ *Revalidation (IQ - OQ - PQ)*

a) Competences

Name and address of institution	
Operator	
Department	
Validator (Name of persons, or companies	
Responsible for overall validation (person designated by operator)	

b) Description of sterilization processes

Only the sterilization procedures with which the sterile barrier system described under c) is sterilized are to be specified

Sterilization processes used in combination with the sterilization sheets	❑ STEAM	❑ EO (Ethylene oxide)	❑ FORM (Formaldehyde)
	❑ VH2O2 (Plasma)	❑ Other	

c) Determining the filling/packaging size

Medical device (Worst Case)	
Packaging size	

d) Description of sterilization sheet

Manufacturer/distributor				
Supplier				
Designation (incl. g/m²)				
CE conformity declaration available?* [44]	❑ Yes	❑ No		
ISO 11607-1 conformity?* [45]	❑ Yes	❑ No		
Description of packaging material (porous material)* [46]	❑ Crepe paper	❑ Nonwovens	❑ SMS nonwovens	❑ Other
Manufacturer's specifications and/or data sheet available?*	❑ Yes	❑ No		
Compatible with sterilization process?*	❑ Yes	❑ No		

44 The CE mark must be affixed to the outer packaging. The CE mark must not be affixed to the sheets supplied by the manufacturer (preformed sterile barrier system).

45 Conformity with ISO 11607-1 is an absolute prerequisite and in general includes conformity with EN 868-2. Often, CE conformity and conformity with ISO 11607 Part 1 are declared jointly in one document.

46 A complete checklist must be completed for each material and the validation process carried out. When using packaging materials in different weights (e.g. g/m²), a worst-case situation must be defined and documented, and this must be checked during performance qualification using a checklist.

Validation IQ

Installation Qualification (IQ) verifies that the instrument or equipment being qualified, as well as its sub-systems and any ancillary systems, have been delivered, installed and configured in accordance with the manufacturer's specifications or installation checklist.

- IQ usually takes place with the manufacturer
- A "real" installation only when using devices (machine processes, sealing devices)
  - ➢ has to be checked and documented
- In addition, this includes the instruction on devices / products, can also be by video
  - ➢ Training must be documented (usually performed by the manufacturer)

Validation IQ

IQ of pouches and reels

- Description of the sealing device
- Installation conditions of the sealing device
- Documentation of correct commissioning
- Description of the monitoring parameters by the device
- Documentation of the briefing
- Standards-compliant devices monitor the critical parameters: temperature, contact force and speed / time

IQ of soft-pack-sheets and containers

- Only manual process without machine support
- Only the instruction training is part of the IQ

BUT:

- There must be standard operating procedures for each system
- These are part of the instruction training

Validation OQ

Operational qualification (OQ) is performed to check that the equipment's performance is consistent with the user requirement specification, within the manufacturer-specified operating ranges.

- Adaptation of the devices / products to the existing process and the environmental conditions
- Specification of the number of samples according to DIN EN ISO 186 (mainly for visual inspections)
- Checking the quality characteristics of a product after production of the packaging
  - Check BEFORE sterilization
  - It is checked whether the process of packaging can be carried out successfully according to the specifications (standard operating instructions / devices) → it is NO validation of sterilization

Validation OQ

OQ of pouches and reels

- Setting the temperature bands of the sealing device (depending on the packaging material, e.g. Tyvek)
- **Test real vs. set temperature**
- Verification of the quality properties of the SEALANT
  - Seal Check
  - Ink test
  - Peel test
  - Visual inspection
- Definition of the specific sealing temperature with automatic shutdown etc.
  - **As a rule, the OQ takes place during the (initial) validation with the**

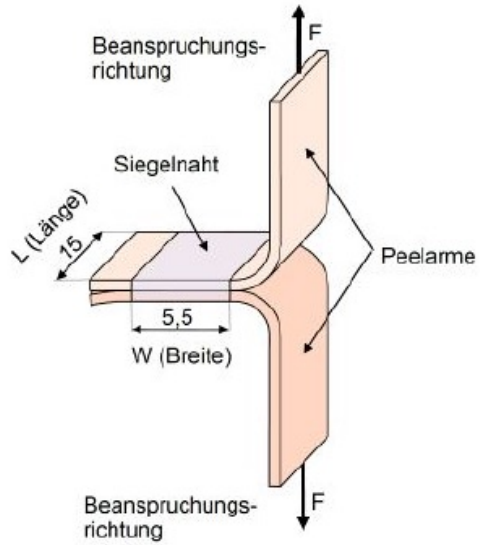
OQ of soft-pack-sheets and containers

- Recheck if the packaging process has been trained
- Determination of a number of samples according to DIN EN ISO 186
  - **As manual process, there are no normative requirements for test tests. Therefore samples and training**
- Checking the quality characteristics of the packaged product by visual inspection and evaluation of the individual samples produced
  - **Best to pack different products with different employees generates the "Worst Case"**

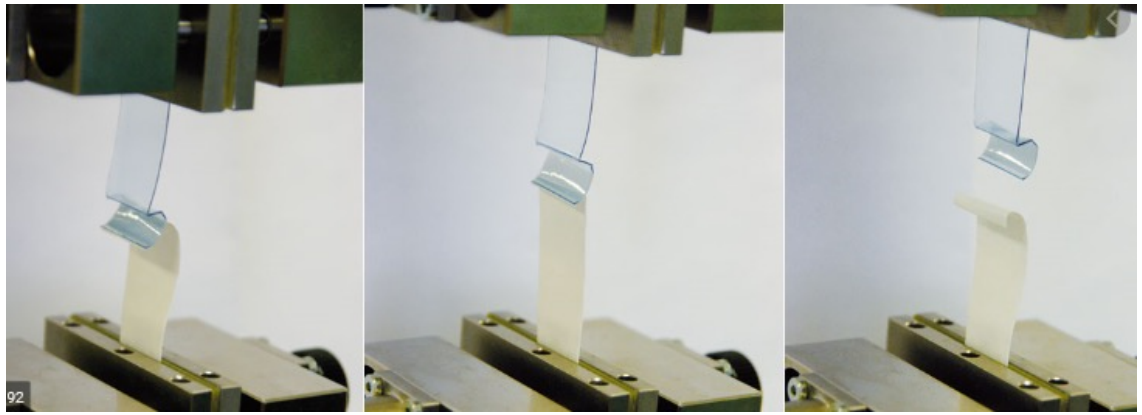
Validation PQ

PQ is the final step in qualification processes for equipment, and this step involves verifying and documenting that the equipment is working **reproducibly** within a specified working range.

- Assessment AFTER sterilization, whether the process is controlled/safe
- The prepared samples are tested in 3 sterilization batches
  → **Multiply when using several sterilization procedures**



- Finally, check the quality characteristics



Quelle: BBF Sterilisationsservice;
https://www.sterixpert.de/de/prueflabor-verpackung.html
abgerufen am 28.08.2020 12:57 Uhr

Validation PQ

PQ of pouches and reels

- Description real / set temperature from OQ
- Sealing parameters are defined per sterilization batch
- Checking the quality properties is done by visual inspection
- Performing a seal strength test according to EN 868-5, Appendix D with the appropriate device (not to be confused with the contact pressure for sealing)
  - → **Sealing seam can be checked at laboratories / manufacturers, or directly in the process**
  - → **It is best to do the entire validation of pouches and reels with the manufacturer / agent**

PQ of soft-pack-sheets and containers

- Checking the quality properties is done by visual inspection
- In addition, checking compliance with the correct packaging technique
  1. visual inspection
  2. Stepwise "backwards packing" - opening the packaging (photo documentation advisable at (first) validation)
  - → **Residual moisture and soiling are not part of the packaging validation but are part of the sterilization validation**
  - → **Only the influence of sterilization on the process of packaging is examined**

Validation Report

- Digital or printed report

- Structure a shown in Guideline
  - Validation plan
  - Evaluation and Results
  - Information on justification and calibration of measurement-devices
  - Definition and intervals of routine checking and follow-up-validations
  - Release by handwritten signature of validator, CSSD-manager, hospital-manager

- Evidence by photoraphies, protcols and checklists as attachement

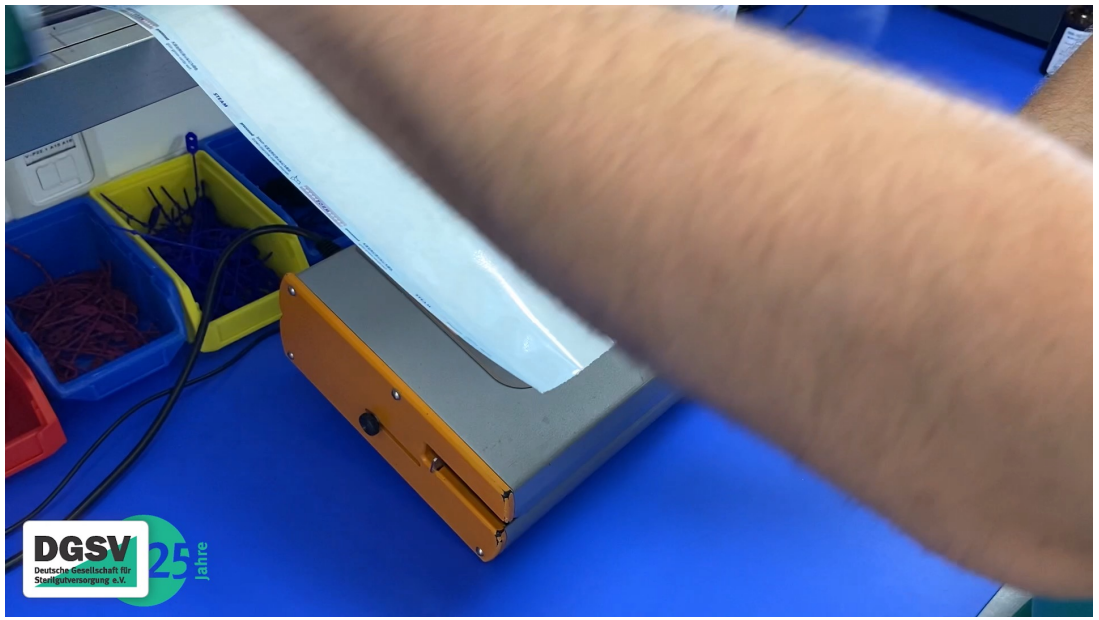
Routine Controls

- Verification of the quality properties of the SEALANT
  - Seal Check
  - Ink test
  - Peel test
  - Visual inspection

- Defining the frequency and nature of the test

Routine Controls – Ink Test

Routine Controls – Peel and Seal Check



Experiences

- The standardization of packaging processes saves resources and time at all
- The “unboxing” of containers or “un-wrapping” of sheets as routine-control is better watched in OR to save repeated reprocessing-cycles
- the packaging of bulky and non-cubic objects is a challenge for the employees, when they are not used to do this often
- Video-based instructions are a good way to reach the employees also in night-shift

- Challenges in future will be the validation of packaging-robots
- There are already robots for wrapping with sheets, packing in pouches and reels and packing of containers in the market
- They have to reach the same safety-level as manual packed goods

Take Home Message/ Summary

- ISO 11607-2 requires the validation of the packaging processes
- IQ / OQ best with manufacturer
  → especially during the sealing process
- Manufacturers offer support
  - example validations
  - Assistance in implementation
- DGSV – Guideline is a very good guide to validation
- Standardization of packaging materials simplifies all processes of validation

→Better standard for the entire processing!

The German Board of DGSV® e.V. wishes you an insightful read and enjoyment of validating