ISO 22441 standard for validation of the H_2O_2 sterilizers explained

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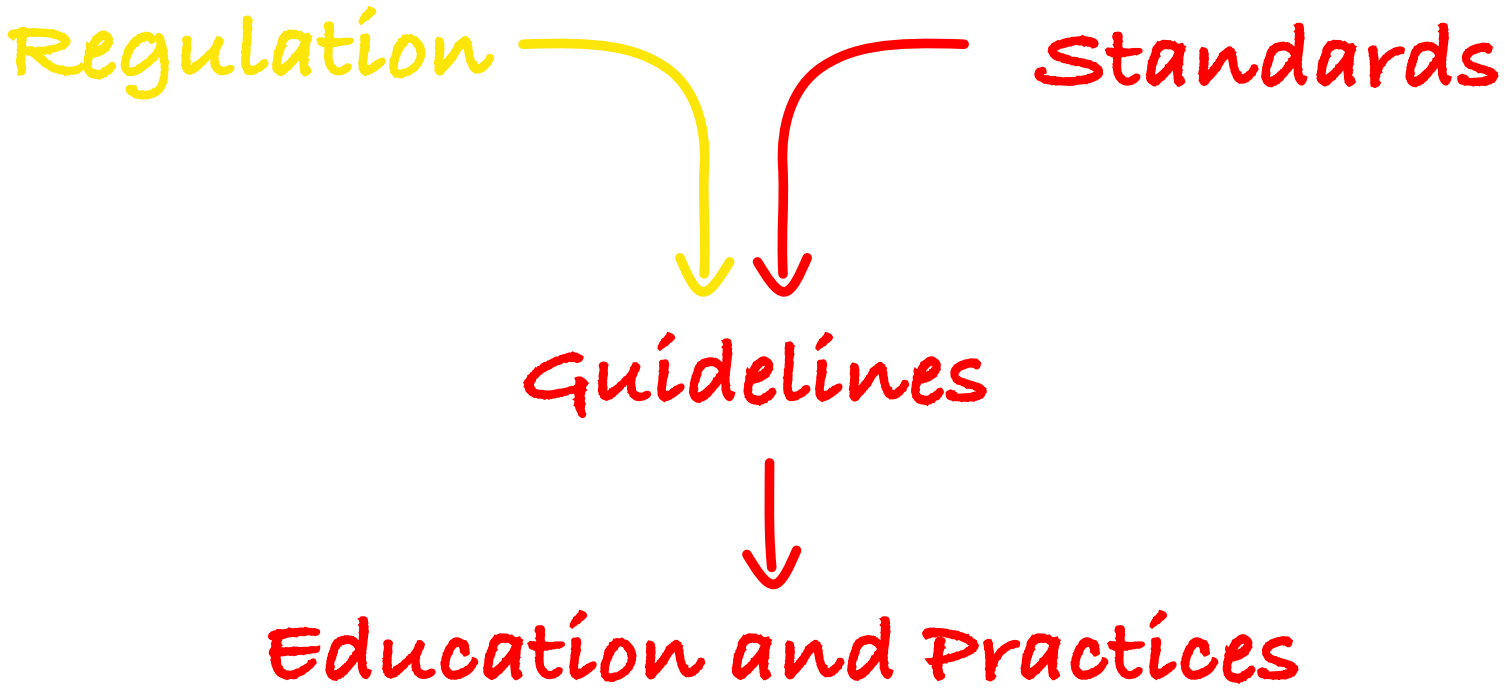
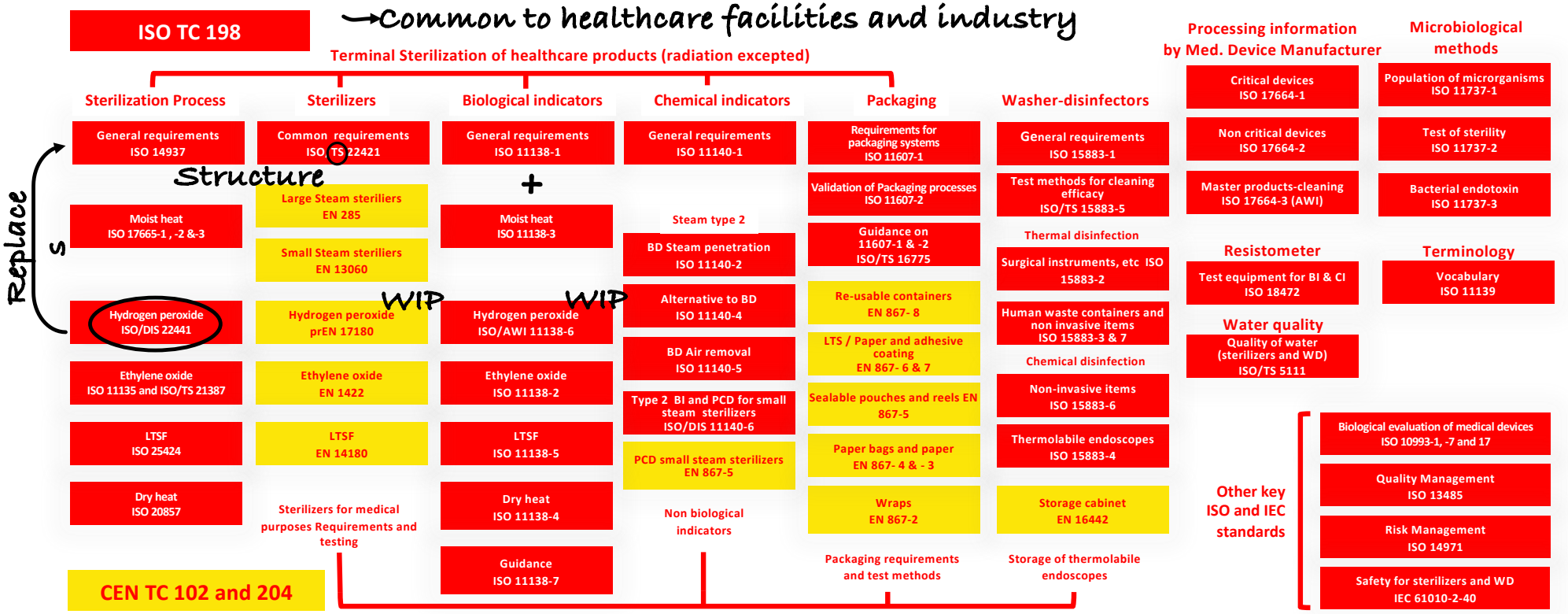
wfhss
World Federation for Hospital Sterilisation Sciences

Introduction



ISO and EN « sterilization » standards



Content & Scope

ISO 22441 - process
1. Scope 2. Normative references 3. Terms and definition 4. Quality Management system elements
5. Sterilization agent characterization
6. Process and equipment characterization
7. Product definition
8. Process definition
9. Validation (IQ, OQ, PQ)
10. Routine monitoring and control
11. Product release from sterilization
12. Maintaining process effectiveness

1. Scope

   Development, validation and routine monitoring and control of a low temperature sterilization process for medical devices using vaporized hydrogen peroxide (VH2O2) as the sterilizing agent

Prion: Not included

Note : some VH2O2 sterilizers have processes that demonstrate some level of inactivation*……

Fichet G et al. Journal of microbiologicam methods - 2007
Roger-Kreuz C et al. Infection control and hospital epidemiology - 2009
https://ansm.sante.fr/vos-demarches/industriel/liste-des-produits-inactivants-et-format-de-dossier-pour-la-revendication-de-performances-dinactivation

EN 17180 (draft)

1. Scope

……

This document specifies minimum requirements:

- for the performance and design of sterilizers intended to deliver a process capable of sterilizing medical devices;
- for the equipment and controls of these sterilizers needed for operation, control, and monitoring, and which can be used for validation of the sterilization processes;
- for the test equipment and test procedures used to verify the sterilizer performance specified by this document.

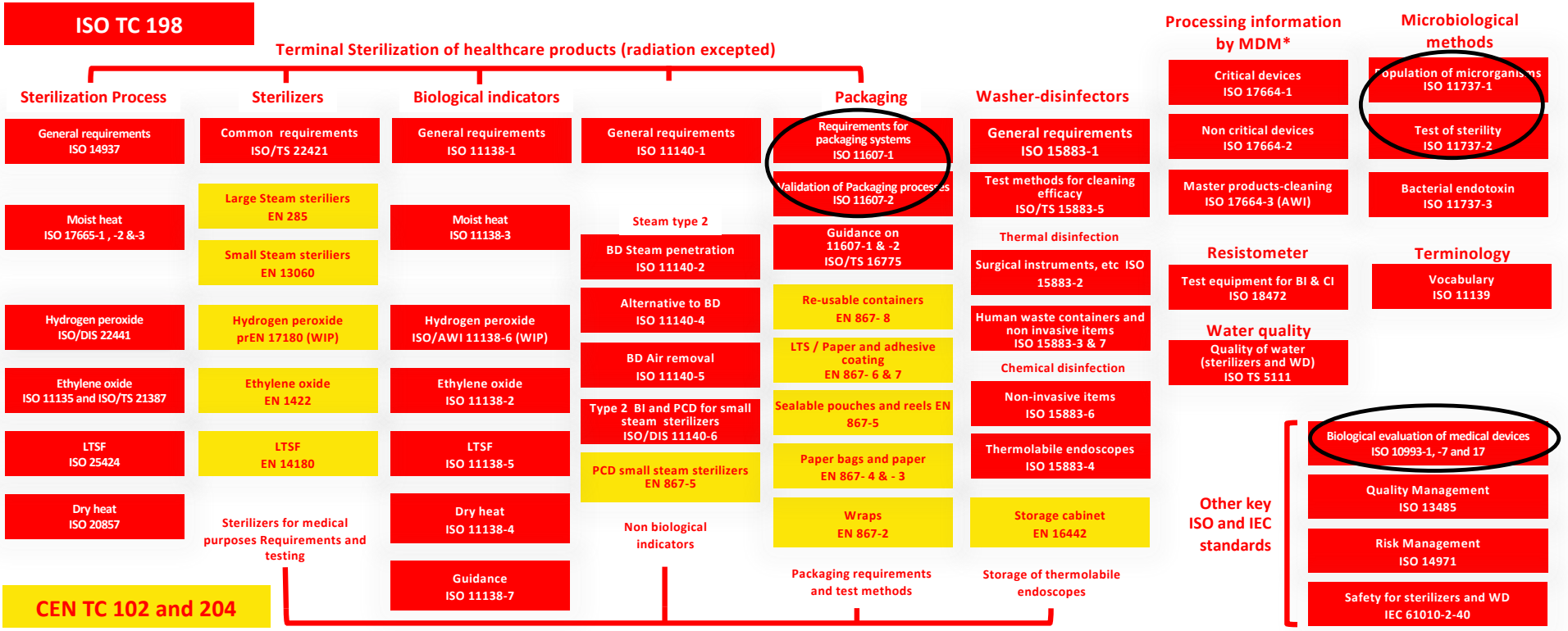
EN 17180 (Draft)
1. Scope 2. Normative references 3. Terms and definition
4. General (Ex : sterilizer types, equipment development …)
5. Equipment design and construction (Ex : safety, vibration …)
6. Indicating, monitoring, controlling and recording
7. Service and local environment (Ex : Sterilant, Electrical supply…)
8. Emissions (Ex : Electromagnetic, Noise, Heat..)
9. Test instrumentation (not fitted to the sterilizer)
10. Performance assessment (penetration with type test device, microbicidal with tests loads)
11. Information to be supplied

ISO 22441 vs EN 17180 (when published)

ISO 22441 - process	prEN 17180
1. Scope 2. Normative references 3. Terms and definition 4. Quality Management system elements	
5. Sterilization agent characterization	
6. Process and equipment characterization	+
7. Product definition	
8. Process definition	
9. Validation (IQ, OQ, PQ)	+
10. Routine monitoring and control	+
11. Product release from sterilization	+
12. Maintaining process effectiveness	+

ISO 22441	EN17180
Medical device	Test device

2.Normative references



* Medical device manufacturers

3. Terms and definitions

Sterilant ⟶ **Sterilizing agent**

H_2O_2 / H_2O solution — Vaporized H_2O_2 + H_2O

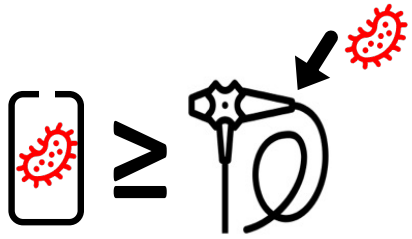
Variables ⟶ **Parameters and tolerances**

P, T°C, t, sterilizing agent Concentration — Specified value for a variable

PCD (process challenge device)

Item providing a defined resistance to a cleaning, disinfection or sterilization process and used to assess performance of the process (ISO 11139)

Note 1 to entry: for the purpose of this document, item means a simulation of a product, a test device, or an inoculated product



8.5 c) and 8.8 of ISO 22441

See also PCD state of the art C. Denis WFHSS 2021

4. QMS elements - Typical responsibilities

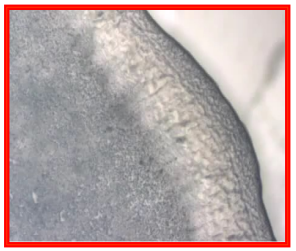
According to informative annex E.4

ISO 22441 - process	HCF*	MDM*	SM*
1. Scope 2. Normative references 3. Terms and definition 4. Quality Management system elements			
5. Sterilization agent characterization			✓
6. Process and equipment characterization			✓
7. Product definition Health care Facility with IFUs provided by MDM	✓	✓	
8. Process definition Sterility and compatibility tests		✓	✓
9. Validation (IQ, OQ, PQ) IQ and OQ subcontracted to the SM. PQ by HCF or subcontracted to SM or 3rd party	✓		
10. Routine monitoring and control	✓		
11. Product release from sterilization	✓		
12. Maintaining process effectiveness rQ, Maintenance	✓		

* HCF: Health care Facility
* MDM: Medical Device Manufacturer
* SM: Sterilizer Manufacturer

Physics of sterilization

- **Sterilization processes are complex, multiphasic, dependent on surfaces properties and geometries. Given the growing complexity of medical devices, modeling remains challenging and microbiology test cannot be avoided**
- **Vacuum to withdraw non-condensable gases but at various levels. Some process variables are common to sterilization modalities (P, T°C, t, sterilizing agent concentration …) but role and range differ**
- **Adsorption, Absorption and condensation but in different ways**
  - Steam: Release of latent heat
  - EO: Humidity to allow penetration of EO in spores
  - LTSF: Effective in liquid phase
  - H_2O_2: Adsorption and highly concentrated condensate
- **Altough useful there are limit to // between modalities. What is good/needed for a given process might not be appropriate for another.**



Physics of sterilization
WFHSS 2022

Daniel Beysens
Nicolas Lavielle

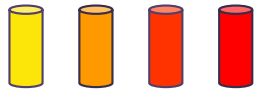
5. Sterilizing agent characterisation

Microbicidal effectiveness

- Geobacillus stearothermophilus
- ISO 11138-1 (ISO 11138-6 when available)

Effect on materials

- Evolution of properties after repeated exposures
- Biological safety according to ISO 10993-1 and 17



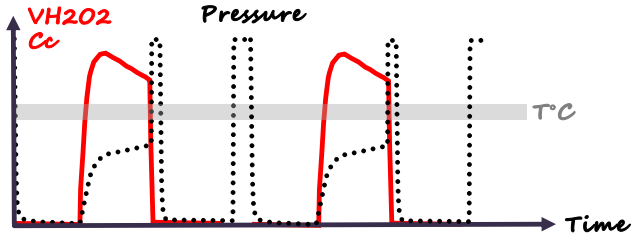
Safety and the environment

6. Process & equipment characterisation

Process characterization

Cycle Variables and parameters:

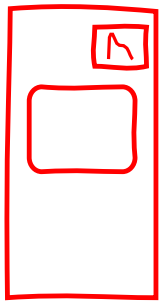
- Time,
- Pressure, Low vacuum
- T°C, Range
- VH2O2 concentration (measured directly or indirectly),



Equipment characterization

Hardware, software, Control & Monitoring

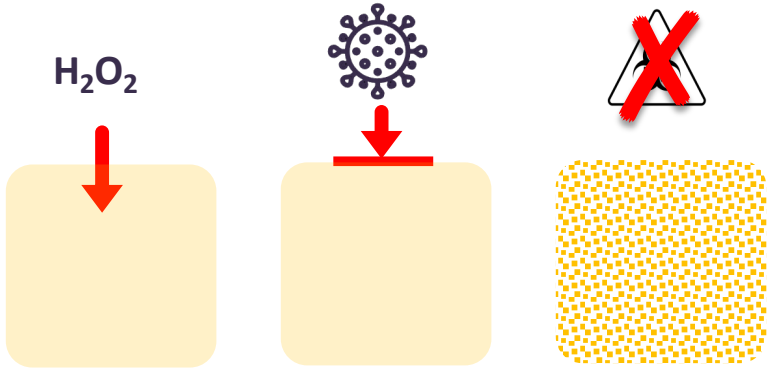
6.3.3 The equipment specification shall confirm that means are provided to ensure that a failure in a control function does not lead to a failure in recording of process parameters such that an ineffective process appears effective



7. Product definition

Packaged Medical device cleaned and prepared according to medical device manufacturer instruction for reprocessing - ISO 17664-1

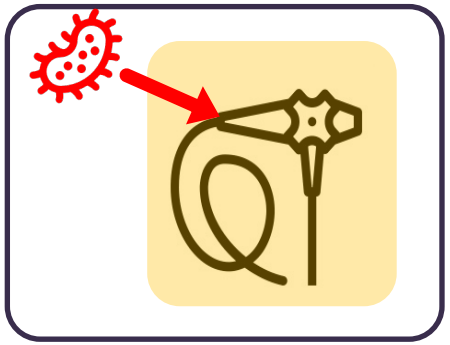
Packaging Validated ISO 11607-1 & 2



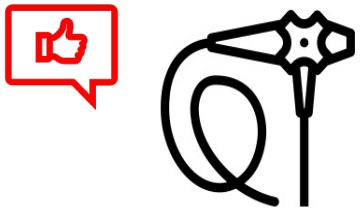
8. Process definition

Sterility tests

- 6 log of geobacillus thermophilus according to overkill principle
- at the most challenging location in the device
- X 3 at ½ cycle

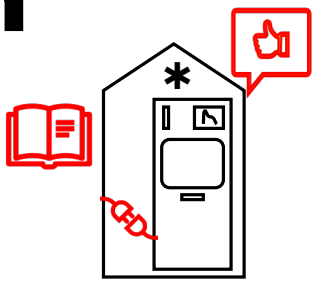


Functionality tests after # of cycles determined by Medical Device Manufacturer



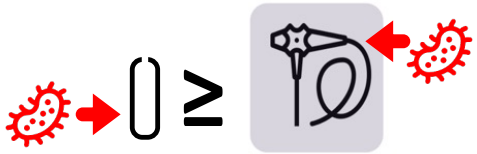
Biological safety evaluation if needed

9. Process validation



1. Installation Qualification and documentation
2. Operational Qualification

3. Performance Qualification – For each cycle
   - Most challenging devices/load configuration 9.4.4 b) e)
   - Packaging ≥ routine 9.4.4.c)
   - BI 9.4.5 compliant to ISO 11138-1 or BI in PCD responding to 8.8
   - CI optional 9.4.5.e). If used might comply to ISO 11140-1
   - ½ cycle – 9.4.3 x 3 9.4.11
   - Independent Control of process parameters + response of BI or BI/PCD



4. Review and approval of IQ, OQ, PQ

9. Process validation – in practice

No normative requirement from ISO 22441 for T°C sensors in load

Note to 9.4.3 one or more test sensors for this purpose are typically located as closely as possible to the positions of the respective sterilization chamber probes

No normative requirement for H_2O_2 concentration monitor in load

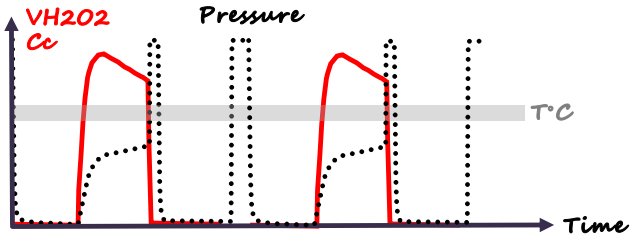
Most challenging routine load with BI *or* BI in a PCD [8.8]

or/and

Challenge pack tested by the manufacturer as more challenging than the most challenging approved routine load, with BI *or* BI in a PCD [8.8]

10. Routine controls

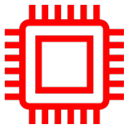
Each cycle, routine monitoring/recording and visual controls
BI/BI in PCD, CI according to applicable recommendations/rules and healthcare facilities procedure



11. Load release

According to healthcare facility procedures

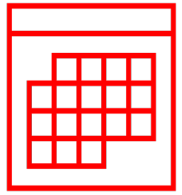
Parametric release or BI release
Often opposed but in fact complementary



Note to 11.3: BIs and CIs are widely used to support product release in healthcare facilities

12. Maintaining process effectiveness

Maintenance and Recalibration



Requalification (planned or as needed)

- **Installation requalification after relocation**
- **Operational requalification**
- **Performance requalification**

Conclusion

Compliance of a VH202 process to ISO 22441

ISO 22441 - process	HCF*	MDM*	SM*
1. Scope 2. Normative references 3. Terms and definition 4. Quality Management system elements			
5. Sterilization agent characterization			✓
6. Process and equipment characterization			✓
7. Product definition (med. device load) HC Facility with IFUs provided by MDM	✓	✓	
8. Process definition Sterility and compatibility tests		✓	✓
9. Validation (IQ, OQ, PQ) IQ and OQ subcontracted to the SM. PQ by HC facility or subcontracted to SM or 3rd party	✓		
10. Routine monitoring and control	✓		
11. Product release from sterilization	✓		
12. Maintaining process effectiveness rQ, Maintenance subcontracted to the SM	✓		

* HCF: Healthcare Facility
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Thank you