Sterilisation Equipment, Characteristics - VALIDATION

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Solutions for Cleaning, Disinfection and Sterilization in Healthcare, the Pharmaceutical Industry and Laboratories
Sterilisation Equipment – Characteristics

VALIDATION

OVERVIEW –
Main criteria:

- Regulatory Requirements
- Measuring Equipment
- Premises and conditions
- Application - Sequence
- Summary
Sterilisation Equipment – Characteristics

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Regulatory Requirements – within the EU

- MDD, (Medical Device Directive) under directive 93/42/EEC.
- EN 554
- EN ISO 17665 Part 1 + 2
- EN ISO 14937
- Regulations from national institutions, RKI*, Swissmedic,
- Recommendations from professional associations and societies

* Robert Koch Institute, Berlin, Germany
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Regulatory Requirements –
EN 554 / EN ISO 17665 Part 1 + 2 and EN ISO 14937

- Requirements according the EN:
  Sterilisation of products and devices for the health care.
  General requirements of the characteristics of the sterilant agent and of the development, validation and monitoring on a routine basis of a sterilization process for medical products.

- The method is based on the monitoring of the physical parameters i.e. (time, temperature and pressure), which are required to produce sterile products.
Only qualified personnel can be responsible for:

- Installation and preventative maintenance
- Validation and routine monitoring
- Release of sterile products
- I.e. Certified and authorized Validation specialist
- Certified according EN ISO 9001:2000
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Regulatory Requirements -
Reference literature

- **ISO-10012-1**: Quality requirements for Measuring systems
  Measuring failure, less than 3-10 times, as the required measuring accuracy

- **EN-554**: Sterilisation of medical products
  Measuring equipment should have 3 times higher measuring accuracy than measured reference point

- **EN-285**: Sterilisation – Steam sterilization – Large sterilizers
  Failure between 0°C and 150°C, should not exceed ± 0.25%
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Measuring Equipment – Overview

1. Temperature Reference
2. Temperature Standard
3. PC + Validation Software
4. Chamber connection – validation
5. Data Logger + Interface
6. Pressure Standard – Calibration
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Measuring Equipment –
Complete System with Thermo elements

- Temperature standard
- Thermo elements
- Temperature reference
- Validator – Data recorder
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Measuring Equipment –
Complete system with Thermo elements

- Temperature reference
- Measuring system
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Measuring Equipment –
Complete system with Data loggers

Data loggers

- Temperature
- Temperature + pressure

- Interface + PC
### Measuring Equipment – Selection – Data recording sensors

<table>
<thead>
<tr>
<th>Feature</th>
<th>Logger</th>
<th>TC’s</th>
</tr>
</thead>
<tbody>
<tr>
<td>Empty Chamber profile</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>Penetration study (hollow tubes)</td>
<td></td>
<td>X</td>
</tr>
<tr>
<td>ETO sterilizers (thermal)</td>
<td>X</td>
<td></td>
</tr>
<tr>
<td>Without Validation port</td>
<td>X</td>
<td></td>
</tr>
<tr>
<td>Online data</td>
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<td>X</td>
</tr>
<tr>
<td>Multiple measuring points</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>Routine control / less measuring points</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>Surface temperatures</td>
<td></td>
<td>X</td>
</tr>
<tr>
<td>Rapid temperature changes</td>
<td></td>
<td>X</td>
</tr>
</tbody>
</table>
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Measuring Equipment –
Norm – Test packs

- Bowie Dick – Test pack
- Bowie Dick – Test sheet
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Measuring Equipment – Balance

According EN 285

- Max. weight 25 kg
- Tolerance ≤ ± 0.001 kg
- Calibrated
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Measuring Equipment –
Documents – Test report

Binder with documents according
EN 554 / EN ISO 17665 Part 1+2
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Premises and conditions –
Example: System with thermo elements

Single steps for the qualification of an autoclave:

- Calibration of the thermo elements – determine tolerances and adjust
- Perform necessary test runs
- Evaluation of the calibration – calibration without adjustments
- Documentation and evaluation
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Premises and conditions –
Recorder with thermo elements

Influence of the measuring accuracy are:

Measuring system:
- Measuring writer
- Sensors (Thermo elements)

Calibration system:
- Temperature reference
- Temperature standard
- Human errors
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Premises and conditions –
Pressure test (EN 554 / EN ISO 17665 Part 1+2 / EN 285)

Testing the steam quality

- Correlation between Temperature and pressure
- Compare measured value with calculated value from the steam pressure scale

Types of sensors and calibration

- Online pressure sensors with fix connection
- Data logger (pressure) data evaluation after process
- Pressure calibration
Premises and conditions –
Failure source - human

- The calibration procedure itself can cause measuring failures. In case of calibration devices which are not operate fully automatically, the user is responsible to control the stability of the measuring standards and also the sensors.
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Premises and conditions –
Calibration system: Reference temperature

Main failure: Transfer calibration failure, Influenced by:

- Thermal transition
- Temperature distribution within des block / bath
- Depth of immersion
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Premises and conditions –
Calibration system: Temperature standard

- All measuring procedures shall be defined on a national or international standard (ISO-120012-1)

- The standard temperature should be therefore calibrated, by a certified institution. (i.e. DKD Laboratory of calibration for temperature).

- The measured tolerance of the standard temperature should be declared at the calibration certificate.
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Premises and conditions – Responsibilities

Belimed

- Preparation of the validation plan
- Measuring defined values
- Documentation of the performed measurement

Customer

- Release of the validation plan
- Provide media supply according DIN
- Define load of sterile goods
- Release of the validation report
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Premises and conditions –
Sequence of the validation procedure

- Installation Qualification (IQ)
- Operational Qualification (OQ)
- Performance Qualification (PQ)
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Application - Sequence

1. Warm up & leak test
2. B & D test
3. Calibration & adjustment of process relevant components
4. Empty chamber profile
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Application – Sequence
Empty chamber profile
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Application - Sequence
Installation Qualification (IQ)

Identification:
- Handbook
- Papers – pressure vessel
- Software version PLC/PC
- Program parameter

Media supply:
- Steam
- Air pressure
- Cold water
- DI / WFI / WBI water
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Application - Sequence
Operation Qualification (OQ)

- Calibration - sterilizer
- Calibration – measuring probes
- Vacuum test (VPR)
- Steam diffusion test (B&D)
- Empty chamber profile
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Application - Sequence
Performance Qualification (PQ)

- Customized loading of sterilization batch cards

- Reference loading are measured (electro-thermal) and documented

- Microbiological evaluation
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Application - Sequence
Test – residual moist

- Before – sterilization process
- After – sterilization process
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Application - Sequence
Visual Test – residual moist
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Application - Sequence Documentation

- Validation report which is clearly arranged and contains all relevant data

- Comprehensive and precise measuring protocols and calculations
Application - Sequence
Release – Documentation through customer
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Summary –
Customer benefit

- Safe sterilization processes (Cleaning, Sterilisation, Packaging)
- High standard and consistent quality of the processed medical products
- Competence about actual norms and regulations.
- Analysis of the loading structure
- Optimized process procedure within the CSSD
- Transparent costs and potential of costs savings.
Thank you for your attention

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