Standards for Reprocessing Processes (1)

CLEANING STERILIZATION

Validation

EN ISO 14937
Requirements for development, validation and routine monitoring of all sterilization processes

EN ISO 11135
EO processes

EN ISO 11137-1 -3
Radiation processes

DIN CEN ISO/TS 13004
Radiation processes

EN ISO 17665-1 -3*
Steam processes

EN ISO 25424
LTSF processes

ISO 22441
H_2O_2 processes

EN ISO 20857
Dry heat processes

EN ISO 17664-1
Information about reprocessing of re-usable medical devices

ISO 17664-2
Non-critical medical devices

DIN 58921
Validation of medical device simulators (MDS)
(English version available)

EN 556-1
Definition:
Sterility Assurance Level

Sterilizers

EN 285
Requirements for large sterilizers (over 54 l)

EN 13060
Requirements for small sterilizers (below 54 l)

EN 14180
Requirements for LTSF sterilizers

EN 1422
Requirements for EO sterilizers

WD 17180
Sterilizer for H2O2 sterilization processes

EN ISO 18472
Requirements for test sterilizers (resistometers)

EN 12347
Biotechnology - Performance criteria for steam sterilizers and autoclaves

Washing Disinfection

EN ISO 15883-1
General Requirements for washer/disinfectors

EN ISO 15883-2
W/D requirements for surgical instruments

EN ISO 15883-3
W/D requirements for containers for human waste

EN ISO 15883-4
W/D requirements for themolabile endoscopes

EN ISO 15883-5
W/Ds – test soils and methods

EN ISO 15883-6
W/Ds – Requirements and tests for general purpose W/Ds with thermal disinfection

EN ISO 15883-7
W/Ds – Requirements and tests for general purpose W/Ds with chemical disinfection for bedframes, containers, etc.

DIN 58341
Requirements for the validation of cleaning & disinfection processes

EN 16442
Storage cabinet for endoscopes

Chemical Indicators

EN ISO 11140-1
General requirements, definition and test procedure for chemical indicators (CI)

EN ISO 11140-3
Requirements for the original BD-test page

EN ISO 11140-4
Test requirements for BD-Simulation tests

ISO 11140-5
Test requirements for the US BD-test

EN ISO 11140-6
Type 2 indicators and PCDs as sterilizer tests
(old: EN 867-5)

EN ISO 15882
Guidance for the selection, use and interpretation of the results for chemical indicators

Biological Indicators

EN ISO 11138-1
General requirements and classifications on Biological indicators (BI)

EN ISO 11138-2
BI for EO sterilization

EN ISO 11138-3
BI for steam sterilization

EN ISO 11138-4
BI for dry heat sterilization

EN ISO 11138-5
BI for LTSF sterilization

EN ISO/WD 11138-6
BI for H_2O_2 sterilization processes

EN ISO 11138-7
Guidance for the selection, use and interpretation of the results for biological indicators
(old: ISO 14161)

EN ISO 11138-8
Biological indicators – Reduced Incubation Time (RIT)

Packaging

EN ISO 11607-1
Packaging of medical devices

EN ISO 11607-2
Validation requirements for forming processes

DIN CEN ISO/TS 16775
Guidance for the application of EN ISO 11607-1+2

EN 868 Series 2-10
Packaging of sterile goods

European Medical Device Regulation (MDR) 2017/745

*Part 2+3 will be deleted and the content will be integrated in the new ISO/CD 17665-2 Moist heat sterilization of medical devices

red = in development

Standards for Reprocessing Processes (2)

CLEANING STERILIZATION

Pharmaceutical Procedures

DIN 58950-1
Definitions

DIN 58950-2
Technical requirements

DIN 58950-3
Tests

DIN 58950-6
Operation

DIN 58950-7
Requirements on services and local environment

Sterilizing agents

EN ISO 14160
Liquid chemical sterilizing agents for medical devices

Disinfectants and disinfectors

EN 1499
Hygienic cleaning of hands

EN 1500
Hygienic hand disinfection

DIN 12353
Preservation of test organisms

EN 17272
Chemical disinfectants and antiseptics für room disinfection

DIN 58949
Steam disinfection apparatus

RKI[1] list of tested disinfectants and disinfection processes

VAH[2] list of disinfectants

Aseptical Production

EN ISO 13408-1
General Requirements

EN ISO 13408-2
Filtration

EN ISO 13408-3
Lyophilization

EN ISO 13408-4
Clean-in-place technologies

EN ISO 13408-5
Sterilization in place

EN ISO 13408-6
Isolator systems

Additional standards

EN 1041
Information supplied by the manufacturer of medical device

EN 15224
Healthcare services

EN ISO 13485
Medical device quality management system

EN ISO 15223-1
Symbols for labeling of medical devices

EN ISO 10993-1 -17
Classification of medical devices

EN 61010-1
General safety requirements for sterilizers and WDs

EN IEC 61010-2
Particular safety requirements for sterilizers and WDs

EN ISO 12100
Safety of machinery – risk assessment

EN 61326-1
EMC requirements for laboratory equipment

ISO/TS 11139
Terms and definitions in sterilization standards

EN ISO 11737-1, -2
Microbiological methods

EN ISO 14971
Risk management of medical devices

EN 15986
Symbols to mark medical devices

DIN 58953-6
Test of microbial barrier of packaging material

DIN 58953-7
Application technology packaging material

DIN 58953-8
Logistic of sterile MD

DIN 58953-9
Application technology sterilization containers

DIN EN 13942
Dentistry –Reprocessing

[1] RKI = Robert Koch Institute, Germany
[2] VAH = Association for applied hygiene, Germany