Standards for Reprocessing Processes (1)

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

EN ISO 14937
also for H_2O_2/ Plasma processes, since no special standard available

ISO/WD 22441
H_2O_2 processes

EN ISO 20857
Dry heat processes

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

ISO/DIS 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

EN ISO 18472
Requirements for test sterilizers (resistometers)

prEN 17180
Sterilizer for H2O2 sterilization processes

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

ISO/TS 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.

EN 16442
Storage cabinet for endoscopes

Chemical Indicators

EN 867-5
Chemical indicator systems for steam sterilizers (Test standard for hollow load test), will be replaced by ISO 11140-6

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

ISO/WD 11140-6
Type 2 indicators and PCDs as sterilizer tests. replacing 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 (old ISO 14161)
Guidance for the selection, use and interpretation of the results for biological indicators

EN ISO/CD 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

red = in development

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

Standards for Reprocessing Processes (2)

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
- **prEN 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 ISO 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