

Standards for Reprocessing Processes (1)

Validation	Sterilizers	Washing Disinfection	Chemical Indicators	Biological Indicators	Packaging
EN ISO 14937 Requirements for development, validation and routine monitoring of all sterilization processes	EN 285 Requirements for large sterilizers (over 54 l)	EN ISO 15883-1 General Requirements for washer/disinfectors	EN 867-5 Chemical indicator systems for steam sterilizers (Test standard for hollow load test), will be replaced by ISO 11140-6	EN ISO 11138-1 General requirements and classifications on Biological indicators (BI)	EN ISO 11607-1 Packaging of medical devices
EN ISO 11135 EO processes	EN 13060 Requirements for small sterilizers (below 54 l)	EN ISO 15883-2 W/D requirements for surgical instruments	EN ISO 11140-1 General requirements, definition and test procedure for chemical indicators (CI)	EN ISO 11138-2 BI for EO sterilization	EN ISO 11607-2 Validation requirements for forming processes
EN ISO 11137-1 -3 Radiation processes	EN 14180 Requirements for LTSF sterilizers	EN ISO 15883-3 W/D requirements for containers for human waste	EN ISO 11140-3 Requirements for the original BD-test page	EN ISO 11138-3 BI for steam sterilization	DIN CEN ISO/TS 16775 Guidance for the application of EN ISO 11607-1+2
DIN CEN ISO/TS 13004 Radiation processes	EN 1422 Requirements for EO sterilizers	EN ISO 15883-4 W/D requirements for thermolabile endoscopes	EN ISO 11140-4 Test requirements for BD-Simulation tests	EN ISO 11138-4 BI for dry heat sterilization	EN 868 Series 2-10 Packaging of sterile goods
EN ISO 17665-1 -3 Steam processes	EN ISO 18472 Requirements for test sterilizers (resistometers)	ISO/TS 15883-5 W/Ds – test soils and methods	ISO 11140-5 Test requirements for the US BD-test	EN ISO 11138-5 BI for LTSF sterilization	
EN ISO 25424 LTSF processes	prEN 17180 Sterilizer for H ₂ O ₂ sterilization processes	EN ISO 15883-6 W/Ds – Requirements and tests for general purpose W/Ds with thermal disinfection	ISO/WD 11140-6 Type 2 indicators and PCDs as sterilizer tests. replacing EN 867-5	EN ISO/WD 11138-6 BI for H ₂ O ₂ sterilization processes	
EN ISO 14937 also for H ₂ O ₂ / Plasma processes, since no special standard available	EN 12347 Biotechnology - Performance criteria for steam sterilizers and autoclaves	prEN ISO 15883-7 W/Ds – Requirements and tests for general purpose W/Ds with chemical disinfection for bedframes, containers, etc.	EN ISO 15882 Guidance for the selection, use and interpretation of the results for chemical indicators	EN ISO/CD 11138-7 (old ISO 14161) Guidance for the selection, use and interpretation of the results for biological indicators	
EN ISO 20857 Dry heat processes		EN 16442 Storage cabinet for endoscopes		EN ISO/CD 11138-8 Biological indicators – Reduced Incubation Time (RIT)	
EN ISO 17664 Information about reprocessing of re-usable medical devices					
DIN 58921 Validation of medical device simulators (MDS) (English version available)					
EN 556-1 Definition: Sterility Assurance Level					

red = new

European Medical Device Regulation (MDR) 2017/745

Standards for Reprocessing Processes (2)

Pharmaceutical Procedures	Sterilizing agents	Disinfectants and disinfectors	Aseptic Production	Additional standards	
DIN 58950-1 Definitions	EN ISO 14160 Liquid chemical sterilizing agents for medical devices	EN 1499 Hygienic cleaning of hands	EN ISO 13408-1 General Requirements	EN 980 Symbols for labeling of medical devices	ISO/TS 11139 Terms and definitions in sterilization standards
DIN 58950-2 Technical requirements		EN 1500 Hygienic hand disinfection	EN ISO 13408-2 Filtration	EN 1041 Information supplied by the manufacturer of medical device	EN ISO 11737-1, -2 Microbiological methods
DIN 58950-3 Tests		DIN 12353 Preservation of test organisms	EN ISO 13408-3 Lyophilization	EN 15224 Healthcare services	EN ISO 14971 Risk management of medical devices
DIN 58950-6 Operation		EN 14476 Virucidal quantitative suspension test for chemical disinfectants and antiseptics	EN ISO 13408-4 Clean-in-place technologies	EN ISO 13485 Medical device quality management system	EN 15986 Symbols to mark medical devices
DIN 58950-7 Requirements on services and local environment		DIN 58949 Steam disinfection apparatus	EN ISO 13408-5 Sterilization in place	EN ISO 15223-1 Symbols for labeling of medical devices	DIN 58953-1 Sterile supply – Terminology, Logistics
	Surgical drapes	DIN 58949 Steam disinfection apparatus	EN ISO 13408-6 Isolator systems	EN ISO 10993-1 -17 Classification of medical devices	DIN 58953-6 Test of microbial barrier of packaging material
		RKI ¹ list of tested disinfectants and disinfection processes		EN 61010-1 General safety requirements for sterilizers and WDs	DIN 58953-7 Application technology packaging material
		VAH ² list of disinfectants		EN ISO 61010-2 Particular safety requirements for sterilizers and WDs	DIN 58953-8 Logistic of sterile MD
	EN 13795 Surgical drapes, gowns and clean air suits General requirements			EN ISO 12100 Safety of machinery – risk assessment	DIN 58953-9 Application technology sterilization containers
				EN 61326-1 EMC requirements for laboratory equipment	E DIN 13942 Dentistry – Reprocessing

¹ RKI = Robert Koch Institute, Germany

² VAH = Association for applied hygiene, Germany