Annex B: Standards

In compliance with the specifications of the standards listed (Table 1) can be presumed to comply with the "state-of-the-art technology". This compilation includes the standards to be considered in the light of hygiene, from which all relevant standards to be selected in accordance with the planned processing responsibility. For tests that are established to guarantee the technical and functional safety, where appropriate further standards might to be taken into consideration. Table 2 also provides information on standardization projects (new work items) in this area.

The column "subclauses of KRINKO recommendation" creates a link between fundamental standards and the relevant sections of the recommendation. The particularly significant standards **for practical application** were **grayed** (see also DIN handbooks 226, 265, 420, 421, 422 and 469). This part of the annex is regularly updated (see also https://www.din.de/de/mitwirken/normenausschuesse/nagesutech/aufbereitung-von-medizinprodukten-113256).

The column “Standard harmonized under Regulation (EU) 2017/745” creates a link between the fundamental standards and the Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC. The standardization request (M/575) of 14 April 2021 for medical devices in support of Regulation (EU) 2017/745 and in vitro diagnostic medical devices in support of Regulation (EU) 2017/746 already lists over 200 standards that are also to be harmonised by 27 May 2024.

Table 1 — Standards

Standard	Title	Subclauses of KRINKO recommendation	Standard harmonised under Regulation (EU) 2017/745[1]
DIN EN 285	Sterilization — Steam sterilizers — Large sterilizers *(applies up to and including the test after installation)*	1.3, 1.4, 2.2.5	X
DIN EN 556-1	Sterilization of medical devices — Requirements for medical devices to be designated "STERILE" — Part 1: Requirements for terminally sterilized medical devices	1.3, 1.4, 2.2.5	
DIN EN 867-5	Non-biological systems for use in sterilizers — Part 5: Specification for indicator systems and process challenge devices for use in performance testing for small sterilizers Type B and Type S	1.3, 1.4, 2.2.4, 2.2.5	

[1] Standards developed under a standardization request are not necessarily cited at the official journal. Manufactures and operators, who uses the above listed standards, need to assure themselves, whether the relevant standard is cited at the official journal (https://ec.europa.eu/health/md_sector/overview_en) under the relevant Directive/Regulation.

Standard	Title	Subclauses of KRINKO recommendation	Standard harmonised under Regulation (EU) 2017/745[1]
	(Parts 1, 3 and 4 replaced by DIN EN ISO 11140-1, 3 and 4; see also DIN EN ISO 18472)		
DIN EN 868	Packaging for terminally sterilized medical devices Part 2: Sterilization wrap — Requirements and test methods; Part 3: Paper for use in the manufacture of paper bags (specified in EN 868-4) and in the manufacture of pouches and reels (specified in EN 868-5) — Requirements and test methods; Part 4: Paper bags — Requirements and test methods; Part 5: Sealable pouches and reels of porous materials and plastic film construction —Requirements and test methods; Part 6: Paper for low temperature sterilization processes — Requirements and test methods; Part 7: Adhesive coated paper for low temperature sterilization processes — Requirements and test methods; Part 8: Re-usable sterilization containers for steam sterilizers conforming to EN 285 — Requirements and test methods; Part 9: Uncoated nonwoven materials of polyolefines — Requirements and test methods; Part 10: Adhesive coated nonwoven materials of polyolefines — Requirements and test methods *(Part 1 replaced by DIN EN ISO 11607-1)*	1.3, 1.4, 2.2.4	
DIN EN 1041	Information supplied by the manufacturer of medical devices *(replaced by DIN EN ISO 20417*)	2.2.6	

Standard	Title	Subclauses of KRINKO recommendation	Standard harmonised under Regulation (EU) 2017/745[1]
DIN EN 1422	Sterilizers for medical purposes — Ethylene oxide sterilizers — Requirements and test methods *(applies up to and including the test after installation)*	1.3, 1.4, 2.2.5	
DIN EN 13060	Small steam sterilizers *(applies up to and including the test after installation)*	1.3, 1.4, 2.2.5	
DIN EN 13795	Surgical clothing and drapes — Requirements and test methods Part 1: Surgical drapes and gowns; Part 2: Clean air suits	1.2.2 1.3, 1.4	
DIN EN 14180	Sterilizers for medical purposes — Low temperature steam and formaldehyde sterilizers — Requirements and testing *(applies up to and including the test after installation)*	1.3, 1.4, 2.2.5	
DIN EN 15224	Quality management systems — EN ISO 9001:2015 for healthcare	1.3, 1.4	
DIN EN 15986	Symbol for use in the labelling of medical devices — Requirements for labelling of medical devices containing phthalates	2.2.6	
DIN EN ISO 10993	Biological evaluation of medical devices Part 1: Evaluation and testing within a risk management system; Part 2: Animal welfare requirements; Part 3: Tests for genotoxicity, carcinogenicity and reproductive toxicity; Part 4: Selection of tests for interactions with blood; Part 5: Tests for in vitro cytotoxicity; Part 6: Tests for local effects after implantation; Part 7: Ethylene oxide sterilization residuals;	1.3, 1.4, 2.2.5, 2.2.8	X (only Part 9, 12 and 23)

Standard	Title	Subclauses of KRINKO recommendation	Standard harmonised under Regulation (EU) 2017/745[1]
	Part 9: Framework for identification and quantification of potential degradation products; Part 10: Tests for irritation and skin sensitization; Part 11: Tests for systemic toxicity; Part 12: Sample preparation and reference materials; Part 13: Identification and quantification of degradation products from polymeric medical devices; Part 14: Identification and quantification of degradation products from ceramics; Part 15: Identification and quantification of degradation products from metals and alloys; Part 16: Toxicokinetic study design for degradation products and leachables; Part 17: Toxicological risk assessment of medical device constituents; Part 18: Chemical characterization of medical device materials within a risk management process; Part 23: Tests for irritation		
DIN EN ISO 11135	Sterilization of health care products — Ethylene oxide — Requirements for the development, validation and routine control of a sterilization process for medical devices *(replaces DIN EN ISO 11135-1 and -2)*	1.3, 1.4, 2.2.5	X
DIN EN ISO 11137	Sterilization of health care products — Radiation Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices; Part 2: Establishing the sterilization dose;	1.3, 1.4, 2.2.5	X (only Part 1)

Standard	Title	Subclauses of KRINKO recommendation	Standard harmonised under Regulation (EU) 2017/745[1]
	Part 3: Guidance on dosimetric aspects of development, validation and routine control *(see also DIN SPEC 13223 identical to DIN CEN ISO/TS 13004)*		
DIN EN ISO 11138	Sterilization of health care products — Biological indicators Part 1: General requirements; Part 2: Biological indicators for ethylene oxide sterilization processes; Part 3: Biological indicators for moist heat sterilization processes; Part 4: Biological indicators for dry heat sterilization processes; Part 5: Biological indicators for low-temperature steam and formaldehyde sterilization processes Part 7: Guidance for the selection, use and interpretation of results Part 8: Method for validation of a reduced incubation time for a biological indicator *(see also DIN EN ISO 18472)*	1.3, 1.4, 2.2.5	
DIN EN ISO 11140	Sterilization of health care products — Chemical indicators Part 1: General requirements; Part 3: Class 2 indicator systems for use in the Bowie and Dick-type steam penetration test; Part 4: Class 2 indicators as an alternative to the Bowie and Dick-type test for detection of steam penetration Part 6: Type 2 indicators and process challenge devices for use in performance testing of small steam sterilizers *(see also DIN EN 867-5 and DIN EN ISO 18472)*	1.3, 1.4, 2.2.5, 2.2.6	

Standard	Title	Subclauses of KRINKO recommendation	Standard harmonised under Regulation (EU) 2017/745[1]
DIN EN ISO 11607	Packaging for terminally sterilized medical devices Part 1: Requirements for materials, sterile barrier systems and packaging systems; Part 2: Validation requirements for forming, sealing and assembly processes *(see also DIN SPEC 58997 identical to DIN CEN ISO/TS 16775)*	1.3, 1.4, 2.2.4	
DIN EN ISO 11737	Sterilization of health care products — Microbiological methods Part 1: Determination of a population of microorganisms on products Part 2: Tests of sterility performed in the definition, validation and maintenance of a sterilization process	1.2	X (only Part 2)
DIN EN ISO 13485	Medical devices — Quality management systems — Requirements for regulatory purposes *(certification of conformity)*	1.3, 1.2.1	X
DIN EN ISO 14161	Sterilization of health care products — Biological indicators — Guidance for the selection, use and interpretation of results *(was replaced by DIN EN ISO 11138-7)*	1.3, 1.4, 2.2.5	
DIN EN ISO 14937	Sterilization of health care products — General requirements for characterization of a sterilizing agent and the development, validation and routine control of a sterilization process for medical devices *(also applies for sterilization processes that have not yet been standardized)*	1.3, 1.4, 2.2.5	
DIN EN ISO 14971	Medical devices — Application of risk management to medical devices	1.2, 1.3, 2.2.3	X

Standard	Title	Subclauses of KRINKO recommendation	Standard harmonised under Regulation (EU) 2017/745[1]
DIN EN ISO 15223-1	Medical devices — Symbols to be used with information to be supplied by the manufacturer — Part 1: General requirements	2.2.6	X
DIN EN ISO 15882	Sterilization of health care products — Chemical indicators — Guidance for selection, use and interpretation of results *(see also series DIN EN ISO 11140)*	1.3, 1.4, 2.2.5	
DIN EN ISO 15883	Washer-disinfectors Part 1: General requirements, terms and definitions and tests; Part 2: Requirements and tests for washer-disinfectors employing thermal disinfection for surgical instruments, anaesthetic equipment, bowls, dishes, receivers, utensils, glassware, etc.; Part 3: Requirements and tests for washer-disinfectors employing thermal disinfection for human waste containers; Part 4: Requirements and tests for washer-disinfectors employing chemical disinfection for thermolabile endoscopes; Part 5: Performance requirements and test method criteria for demonstrating cleaning efficacy*;* Part 6: Requirements and tests for washer-disinfectors employing thermal disinfection for non-invasive, non-critical medical devices and healthcare equipment; Part 7: Requirements and tests for washer-disinfectors employing chemical disinfection for non-invasive, non-critical thermolabile medical devices and healthcare equipment (*Validation and Operation)*	1.3, 1.4, 2.2.2	

Standard	Title	Subclauses of KRINKO recommendation	Standard harmonised under Regulation (EU) 2017/745[1]
DIN EN ISO 17664-1	Processing of health care products — Information to be provided by the medical device manufacturer for the processing of medical devices — Part 1: Critical and semi-critical medical devices *(Note: ISO 17664-2, Processing of health care products - Information to be provided by the medical device manufacturer for the processing of medical devices - Part 2: Non-critical medical devices was published in 2021 and adoption as EN ISO is in progress).*	1.2.2, 2.2.6	X
DIN EN ISO 17665-1	Sterilization of health care products — Moist heat — Part 1: Requirements for the development, validation and routine control of a sterilization process for medical devices *(Note: DIN EN ISO 17665-1 and DIN ISO/TS 17665-2 will be replaced by DIN EN ISO 17665, which is currently in the draft stage).*	1.3, 1.4, 2.2.5	
DIN ISO/TS 17665-2	Sterilization of health care products — Moist heat — Part 2: Guidance on the application of ISO 17665-1 *(Attention: Technical Specification)*	1.3, 1.4, 2.2.5	
DIN EN ISO 18472	Sterilization of health care products — Biological and chemical indicators — Test equipment	1.3, 1.4, 2.2.5	
DIN EN ISO 20417	Medical devices — Information to be supplied by the manufacturer *(replaces DIN EN 1041)*	2.2.6	
DIN EN ISO 20857	Sterilization of health care products — Dry heat — Requirements for the development, validation and routine control of a sterilization process for medical devices	1.3, 1.4, 2.2.5	
DIN EN ISO 25424	Sterilization of health care products — Low temperature steam and formaldehyde — Requirements for development, validation and routine control of a sterilization process for medical devices *(replaces DIN EN 15424)*	1.3, 1.4, 2.2.5	X

Standard	Title	Subclauses of KRINKO recommendation	Standard harmonised under Regulation (EU) 2017/745[1]
DIN CEN ISO/TS 13004 (identical to DIN SPEC 13223)	Sterilization of health care products — Radiation — Substantiation of selected sterilization dose: Method VD_{max}^{SD} *(see also series DIN EN ISO 11137)* *(Note: ISO/TS 13004 has been published as ISO and is in the process of being adopted as EN ISO 13004).*	1.3, 1.4, 2.2.5	
DIN 58341	Requirements for the validation of cleaning and disinfection processes	1.3, 1.4, 2.2.2	
DIN 58921	Test method to demonstrate the suitability of a medical device simulator during steam sterilisation — Medical device simulator testing *(standard available in German and English)*	1.3, 1.4, 2.2.5	
DIN SPEC 58929	Operation of small steam sterilizers in the health-care system — Guidance for validation and routine control of sterilization processes	1.3, 1.4. 2.2.5	
DIN 58946-7	Sterilization — Steam sterilizers — Part 7: Edificial preconditions, requirements for the services and the operation of steam sterilizers used in health care facilities	2.2.5	
DIN 58948-7	Sterilization — Low temperature sterilizers — Part 7: Requirements for the installation and operation of ethylene oxide sterilizers and their supply sources	1.3, 1.4, 2.2.5	
DIN 58948-17	Sterilization — Low temperature sterilizers — Part 17: Requirements for the installation and operation of low temperature steam formaldehyde and formaldehyde sterilizers and their supply sources	1.3, 1.4, 2.2.5	

Standard	Title	Subclauses of KRINKO recommendation	Standard harmonised under Regulation (EU) 2017/745[1]
DIN 58949	Disinfection — Steam disinfection-apparatus Part 2: Requirements; Part 3: Efficiency testing; Part 4: Biological indicators for efficacy tests; Part 6: Operation of steam disinfection apparatus, their requirements for the installation and their supply sources (*replaces DIN 58949-6 and -7*)	1.3, 1.4, 2.2.2	
DIN 58952	Sterilization — Transport baskets for sterile barrier systems Part 2: Sterilizing baskets made of metal; Part 3: Instrument trays for sterilizing goods made of metal	1.3, 1.4, 2.2.4, 2.2.5	
DIN 58953	Sterilization — Sterile supply Part 6: Microbial barrier testing of packaging materials for medical devices which are to be sterilized; Part 7: Use of sterilization paper, nonwoven wrapping material, paper bags and sealable pouches and reels; Part 8: Logistics of sterile medical devices; Part 9: Use of sterilization container	2.2.4, 3	
DIN CEN ISO/TS 16775 (identical to DIN SPEC 58997)	Packaging for terminally sterilized medical devices — Guidance on the application of ISO 11607-1 and ISO 11607-2 *(see also series DIN EN 868 and DIN EN ISO 11607)*	1.3, 1.4, 2.2.4	

Table 2 – New work items

New work items	Title	Subclauses of KRINKO recommendation
E DIN EN 17180	Sterilizers for medical purposes — Low temperature vaporized hydrogen peroxide sterilizers — Requirements and testing *(applies up to and including the test after installation)*	1.3, 1.4, 2.2.5
E DIN EN ISO 17665	Sterilization of health care products — Moist heat — Requirements for the development, validation and routine control of a sterilization process for medical devices	1.3, 1.4, 2.2.5