CEN-CENELEC Technical Committees / Bodies for healthcare standards, and their harmonised standards (updated 6-12-2024)

Number Name	Harmonised standards for the MDR and IVDR (standardisation request M/575)	Adopted and published in the OJEU	EN ISO 13485
		Adopted and to be published in the OEJU	EN 60118-0
		Final stages of adoption	EN ISO 80369-1
		Planned	ISO 18250-1
CEN-CLC/JTC 3 Quality management and corresponding general aspects for medical devices	EN ISO 13485 *Medical devices - Quality management systems - Requirements for regulatory purposes* EN ISO 14971 *Medical devices - Application of risk management to medical devices* EN ISO 15223-1 *Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied* ISO 18250-1, -2, -3, -4, -5 *Medical devices - Connectors for reservoir delivery systems for healthcare applications* ISO 20417 *Medical devices - Information to be provided by the manufacturer* EN ISO 80369-1, -2, -3, -5, -6, -7, -20 *Small-bore connectors for liquids and gases in healthcare applications*		
CEN SS F16 Graphical symbols	EN ISO 7010 *Graphical symbols - Safety colours and safety signs*		
CEN-CLC/JTC 16 CEN-CENELEC Joint Technical Committee on Active Implantable Medical Devices	ISO 14708-1, -2, -3, -4, -5, -6, -7 *Implants for surgery - Active implantable medical devices*		
CLC SR 29 Electroacoustics	EN 60118-0, -13 *Electroacoustics - Hearing aids* EN IEC 60601-2-66 *Medical electrical equipment - Part 2-66: Particular requirements for the basic safety and essential performance of hearing aids and hearing aid systems*		
CEN/TC 55 Dentistry			
CLC/TC 62 Electrical equipment in medical practice	EN 50637 *Medical electrical equipment - Particular requirements for the basic safety and essential performance of medical beds for children* EN 60601-1, -1-2, -1-3, -1-6, -1-8, -1-10, -1-11, -1-12, -2-1, -2-2, -2-3, -2-4, -2-5, -2-6, -2-8, -2-10, -2-11, -2-16, -2-17, -2-18, -2-19, -2-20, -2-21, -2-22, -2-23, -2-24, -2-25, -2-27, -2-28, -2-29, -2-31, -2-33, -2-34, -2-36, -2-37, -2-39, -2-40, -2-41, -2-43, -2-44, -2-45, -2-46, -2-47, -2-50, -2-52, -2-54, -2-57, -2-62, -2-63, -2-64, -2-65, -2-68, -2-75, -2-76, -2-83 *Medical electrical equipment* EN 62083 *Medical electrical equipment - Requirements for the safety of radiotherapy treatment planning systems* EN 62304 *Medical device software - Software life-cycle processes* EN 62366-1 *Medical devices - Application of usability engineering to medical devices* EN 80001-1 *Safety, effectiveness and security in the implementation and use of connected medical devices or connected health software* EN IEC 80601-2-26, -2-30, -2-35, -2-49, -2-56, -2-58, -2-59, -2-60, -2-69, -2-71, -2-77, -2-78, -2-86, -2-89 *Medical electrical equipment* EN IEC 81001-5-1 *Health software and health IT systems safety, effectiveness and security - Part 5-1: Security - Activities in the product life cycle* EN 82304-1 *Health software*		
CLC TC 65X Industrial-process measurement, control and automation	EN 61326-1, -2-6 *Electrical equipment for measurement, control, and laboratory use - EMC requirements*		
CLC TC 66X Safety of measuring, control, and laboratory equipment	EN IEC 61010-1, -2-040, -2-101 *Safety requirements for electrical equipment for measurement, control, and laboratory use*		
CEN/TC 102 Sterilizers and associated equipment for processing of medical devices	EN 285 *Sterilization - Steam sterilizers* EN 1422 *Sterilizers for medical purposes - Ethylene oxide sterilizers* EN ISO 11140-1, -3, -4, -6 *Sterilization of health care products - Chemical indicators* EN ISO 11607-1, -2 *Packaging for terminally sterilized medical devices* EN 13060 *Small steam sterilizers* EN 14180 *Sterilizers for medical purposes - Low temperature steam and formaldehyde sterilizers* EN 14222 *Stainless steel steam boilers*		

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	EN ISO 15883-1, -2, -3, -4, -5, -6, -7 *Washer-disinfectors* EN 17180 *Sterilizers for medical purposes - Low temperature vapourized hydrogen peroxide sterilizers*		
CEN/TC 123 Lasers and photonics	EN ISO 11810 *Lasers and laser-related equipment - Test method and classification for the laser resistance of surgical drapes and/or patient protective covers* EN ISO 11990 *Lasers and laser-related equipment - Determination of laser resistance of tracheal tube shaft and tracheal cuffs* ISO 22248 *Lasers and laser-related equipment - Test methods for laser-induced damage threshold - Classification of medical beam delivery systems*		
CEN/TC 140 In vitro diagnostic medical devices	EN 13532 *General requirements for in vitro diagnostic medical devices for self-testing* EN 13612 *Performance evaluation of in vitro diagnostic medical devices* EN 13641 *Elimination or reduction of risk of infection related to in vitro diagnostic reagents* EN 13975 *Sampling procedures used for acceptance testing of in vitro diagnostic medical devices - Statistical aspects* EN 14136 *Use of external quality assessment schemes in the assessment of the performance of in vitro diagnostic examination procedures* EN ISO 15193 *In vitro diagnostic medical devices - Measurement of quantities in samples of biological origin - Requirements for content and presentation of reference measurement procedures* EN ISO 15194 *In vitro diagnostic medical devices - Measurement of quantities in samples of biological origin - Requirements for certified reference materials and the content of supporting documentation* EN ISO 15197 *In vitro diagnostic test systems - Requirements for blood-glucose monitoring systems for self-testing in managing diabetes mellitus* EN ISO 17511 *In vitro diagnostic medical devices - Requirements for establishing metrological traceability of values assigned to calibrators, trueness control materials and human samples* EN ISO 18113-1, -2, -3, -4, -5 *In vitro diagnostic medical devices - Information supplied by the manufacturer (labelling)* EN ISO 20916 *In vitro diagnostic medical devices - Clinical performance studies using specimens from human subjects - Good study practice* EN ISO 23640 *In vitro diagnostic medical devices - Evaluation of stability of in vitro diagnostic reagents*		
CEN/TC 170 Ophthalmic optics	EN ISO 12870 *Ophthalmic optics - Spectacle frames - Requirements and test methods* EN 14139 *Ophthalmic optics - Specifications for ready-to-wear spectacles* EN ISO 14889 *Ophthalmic optics - Spectacle lenses - Fundamental requirements for uncut finished lenses* EN ISO 15004-1 *Ophthalmic instruments - Fundamental requirements and test methods* EN ISO 21987 *Ophthalmic optics - Mounted spectacle lenses*		
CEN/TC 204 Sterilization of medical devices	EN 556-1, -2 *Sterilization of medical devices - Requirements for medical devices to be designated "STERILE"* EN ISO 11135 *Sterilization of health-care products - Ethylene oxide* EN ISO 11137-1, -2 *Sterilization of health care products - Radiation* EN ISO 11737-1, -2, -3 *Sterilization of medical devices - Microbiological methods* EN ISO 13004 *Sterilization of health care products - Radiation* EN ISO 13408-1, -2, -3, -4, -5, -6, -7 *Aseptic processing of health care products* EN ISO 14160 *Sterilization of health care products - Liquid chemical sterilizing agents for single-use medical devices utilizing animal tissues and their derivatives* 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* EN ISO 17664-1, -2 *Processing of health care products - Information to be provided by the medical device manufacturer for the processing of medical devices* EN ISO 17665 *Sterilization of health care products - Moist heat* ISO 18362 *Manufacture of cell-based health care products - Control of microbial risks during processing* EN ISO 20857 *Sterilization of health care products - Dry heat* EN ISO 22441 *Sterilization of health care products - Low temperature vaporized hydrogen peroxide* EN ISO 25424 *Sterilization of health care products - Low temperature steam and formaldehyde*		
CEN/TC 205 Non-active medical devices	EN 455-1, -2, -3, 4 *Medical gloves for single use* EN ISO 1135-4, -5 *Transfusion equipment for medical use* EN ISO 4074 *Natural rubber latex male condoms* EN 13795-1, -2 *Surgical clothing and drapes - Requirements and test methods* EN 14683 *Medical face masks - Requirements and test methods*		

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	EN ISO 23908 *Sharps injury protection - Requirements and test methods - Sharps protection features for single-use hypodermic needles, introducers for catheters and needles used for blood sampling* *Respiratory infection prevention devices for self- and third party protection - Requirements for different performance classes and test methods*		
CEN/TC 206 Biological and clinical evaluation of medical devices	EN ISO 10993-1, -3, -4, -5, 6-, -7, -9, -10, -11, -12, -13, -14, -15, -16, -17, -18, -23 *Biological evaluation of medical devices* EN ISO 14155 *Clinical investigation of medical devices for human subjects - Good clinical practice* EN ISO 18969 *Clinical evaluation of medical devices* EN ISO 22442-1, -2, -3 *Medical devices utilizing animal tissues and their derivatives*		
CEN/TC 215 Respiratory and anaesthetic equipment	EN ISO 5359 *Anaesthetic and respiratory equipment - Low-pressure hose assemblies for use with medical gases* EN ISO 5362 *Anaesthetic reservoir bags* EN ISO 5367 *Anaesthetic and respiratory equipment - Breathing sets and connectors* EN ISO 7396-1, -2, -3 *Medical gas pipeline systems* EN ISO 10524-1, -2, -3 *Pressure regulators for use with medical gases* EN ISO 10651-4, -5 *Lung ventilators* EN ISO 11197 *Medical supply units* EN ISO 15001 *Anaesthetic and respiratory equipment - Compatibility with oxygen* EN ISO 16571 *Systems for evacuation of plume generated by medical devices* ISO 17256 *Anaesthetic and respiratory equipment - Respiratory therapy tubing and connectors* EN ISO 17510 *Medical devices - Sleep apnoea breathing therapy - Masks and application accessories* ISO 18190 *Anaesthetic and respiratory equipment - General requirements for airways and related equipment* EN ISO 18562-1, -2, -3, -4 *Biocompatibility evaluation of breathing gas pathways in healthcare applications* EN ISO 18777-1, -2 *Transportable liquid oxygen systems for medical use* ISO 19211 *Anaesthetic and respiratory equipment - Fire-activated oxygen shut-off devices for use during oxygen therapy* EN ISO 20789 *Anaesthetic and respiratory equipment - Passive humidifiers* EN ISO 23328-1, -2 *Breathing system filters for anaesthetic and respiratory use* EN ISO 23747 *Anaesthetic and respiratory equipment - Peak expiratory flow meters for the assessment of pulmonary function in spontaneously breathing humans* EN ISO 26782 *Anaesthetic and respiratory equipment - Spirometers intended for the measurement of time forced expired volumes in humans* EN ISO 80601-2-12, -2-13, -2-55, -2-61, -2-67, -2-70, -2-72, -2-74, -2-79, -2-80, -2-84, -2-85, -2-87, -2-90 *Medical electrical equipment*		
CEN/TC 216 Chemical disinfectants and antiseptics	EN 13624 *Chemical disinfectants and antiseptics - Quantitative suspension test for the evaluation of fungicidal or yeasticidal activity in the medical area* EN 13727 *Chemical disinfectants and antiseptics - Quantitative suspension test for the evaluation of bactericidal activity in the medical area* EN 14348 *Chemical disinfectants and antiseptics - Quantitative suspension test for the evaluation of mycobactericidal activity of chemical disinfectants in the medical area including instrument disinfectants* EN 14476 *Chemical disinfectants and antiseptics - Quantitative suspension test for the evaluation of virucidal activity in the medical area* EN 14561 *Chemical disinfectants and antiseptics - Quantitative carrier test for the evaluation of bactericidal activity for instruments used in the medical area* EN 14562 *Chemical disinfectants and antiseptics - Quantitative carrier test for the evaluation of fungicidal or yeasticidal activity for instruments used in the medical area* EN 14563 *Chemical disinfectants and antiseptics - Quantitative carrier test for the evaluation of mycobactericidal or tuberculocidal activity of chemical disinfectants used for instruments in the medical area* EN 14885 *Chemical disinfectants and antiseptics - Application of European standards for chemical disinfectants and antiseptics* EN 16615 *Chemical disinfectants and antiseptics - Quantitative test method for the evaluation of bactericidal and yeasticidal activity on non-porous surfaces with mechanical action employing wipes in the medical area* EN 16616 *Chemical disinfectants and antiseptics - Chemical-thermal textile disinfection* EN 16777 *Chemical disinfectants and antiseptics - Quantitative non-porous surface test without mechanical action for the evaluation of virucidal activity of chemical disinfectants used in the medical area* EN 17111 *Chemical disinfectants and antiseptics - Quantitative carrier test for the evaluation of virucidal activity for instruments used in the medical area* EN 17126 *Chemical disinfectants and antiseptics - Quantitative suspension test for the evaluation of sporicidal activity of chemical disinfectants in the medical area*		

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	EN 17387 *Chemical disinfectants and antiseptics - Quantitative test for the evaluation of bactericidal and yeasticidal and/or fungicidal activity of chemical disinfectants in the medical area on non-porous surfaces without mechanical action*		
CEN/TC 239 Rescue systems	EN 1865-1, -2, -3, -4, -6 *Patient handling equipment used in road ambulances* EN 13718-1 *Medical vehicles and their equipment - Air ambulances* EN 13976-1, -2 *Rescue systems - Transportation of incubators*		
CEN/TC 258 Clinical investigation of medical devices			
CEN/TC 285 Non-active surgical implants	EN ISO 5840-1, -2, -3 *Cardiovascular implants - Cardiac valve prostheses* EN ISO 7197 *Neurosurgical implants - Sterile, single-use hydrocephalus shunts and components* EN ISO 9713 *Neurosurgical implants - Self-closing intracranial aneurysm clips* EN ISO 12417-1 *Cardiovascular implants and extracorporeal systems - Vascular device-drug combination products* EN ISO 14602 *Non-active surgical implants - Implants for osteosynthesis* EN ISO 14607 *Non-active surgical implants - Mammary implants* EN ISO 14630 *Non-active surgical implants - General requirements* EN ISO 16061 *Instruments for use in association with non-active surgical implants - General requirements* EN ISO 21534 *Non-active surgical implants - Joint replacement implants - Particular requirements* EN ISO 21535 *Non-active surgical implants - Joint replacement implants - Specific requirements for hip-joint replacement implants* EN ISO 21536 *Non-active surgical implants - Joint replacement implants - Specific requirements for knee-joint replacement implants* EN ISO 25539-1, -2, -3 *Cardiovascular implants - Endovascular devices*		
CEN/TC 293 Assistive products for persons with disability	EN 1985 *Walking aids* EN ISO 10328 *Prosthetics - Structural testing of lower-limb prostheses - Requirements and test methods* EN ISO 10535 *Hoists for the transfer of disabled persons - Requirements and test methods* EN 12183 *Manual wheelchairs - Requirements and test methods* EN 12184 *Electrically powered wheelchairs, scooters and their chargers - Requirements and test methods* ISO 17966 *Assistive products for personal hygiene that support users - Requirements and test methods* ISO 21856 *Assistive products - General requirements and test methods* EN ISO 22523 *External limb prostheses and external orthoses - Requirements and test methods* EN ISO 22675 *Prosthetics - Testing of ankle-foot devices and foot units - Requirements and test methods*		
CEN/TC 316 Medical products utilizing cells, tissues and/or their derivatives			
CEN/TC 362 Project Committee - Healthcare services - Quality management systems			
CEN/TC 367 Project Committee - Breath-alcohol testers			

Sources:

- CEN-CENELEC Healthcare - Technical bodies https://www.cencenelec.eu/areas-of-work/cen-sectors/healthcare/
- Medical devices - Harmonised standards https://health.ec.europa.eu/medical-devices-topics-interest/harmonised-standards_en