General Medical Devices Harmonized Standards

Note: This list of General Medical Devices Harmonized Standards is from the Web Site: http://www.newapproach.org

European Standards Bodies	Standard reference	Titles	Ratification date	Publication OJ
CEN	EN 285	Sterilization - Steam sterilizers - Large sterilizers	1996	C 181 of 1999-06-26
CEN	EN 455-1	Medical gloves for single use - Part 1 : Requirements and testing for absence of holes	1993	C 181 of 1999-06-26
CEN	EN 455-2	Medical gloves for single use - Part 2 : Requirements and testing for physiological properties	1995	C 181 of 1999-06-26
CEN	EN 455-3	Medical gloves for single use – Part 3: Requirements and testing for biological evaluation	1999	C 293 of 2000-10-14
CEN	EN 475	Medical devices. Electrically generated alarm signals	1995	C 181 of 1999-06-26
CEN	EN 540	Clinical investigation of medical devices for humans	1993	C 181 of 1999-06-26
CEN	EN 550	Sterilization of medical devices - Validation and routine control of ethylene oxide sterilisation	1994	C 181 of 1999-06-26
CEN	EN 552	Sterilization of medical devices - Validation and routine control of sterilisation by irradiation	1994	C 181 of 1999-06-26
CEN	EN 552 A1	Sterilization of medical devices - Validation and routine control of sterilisation by irradiation	1994 1999	C 288 of 1999-10-09
CEN	EN 554	Sterilization of medical devices - Validation and routine control of sterilisation by moist heat	1994	C 181 of 1999-06-26
CEN	EN 556	Sterilization of medical devices - requirements for medical devices to be labelled sterile	1994	C 181 of 1999-06-26
CEN	EN 600	Natural rubber latex male condoms	1996	C 181 of 1999-06-26
CEN	EN 724	Guidance on the application of EN 29001 and EN 46001 and of EN 29002 and EN 46002 for non-active medical devices	1994	C 181 of 1999-06-26
CEN	EN 737-1	Medical gas pipeline systems - Part 1: Terminal units for compressed medical gases and vacuum	1998	C 181 of 1999-06-26
CEN	EN 737-2	Medical gas pipeline systems - Part 2: Anaesthetic gas scavening disposal systems - Basic requirements	1998	C 181 of 1999-06-26

CEN	EN 737-2/A1	Medical gas pipeline systems – Part 2: Anaesthetic gas scavenging disposal systems - Basic requirements	1998 1999	C 293 of 2000-10-14
CEN	EN 737-3	Medical gas pipeline systems - Part 3: Pipelines for compressed medical gases and vacuum	1998	C 227 of 1999-08-10
CEN	EN 737-3/A1	Medical gas pipeline systems - Part 3: Pipelines for compressed medical gases and vacuum	1998 1999	C 293 of 2000-10-14
CEN	EN 737-4	Medical gas pipeline systems - Part 4: Terminal units for anaesthetic gas scavenging systems	1998	C 181 of 1999-06-26
CEN	EN 738-1	Pressure regulators for use with medical gases – Part 1: pressure regulators and pressure regulators with flow metering devices	1997	C 181 of 1999-06-26
CEN	EN 738-2	Pressure regulators for use with medical gases - Part 2: Manifold and line pressure regulators	1998	C 293 of 2000-10-14
CEN	EN 738-3	Pressure regulators for use with medical gases - Part 3: Pressure regulators integrated with cylinder valves	1998	C 293 of 2000-10-14
CEN	EN 738-4	Pressure regulators for use with medical gases - Part 4: Low-pressure regulators intended for incorporation into medical equipment	1998	C 293 of 2000-10-14
CEN	EN 739	Low pressure hose assemblies for use with medical gases	1998	C 181 of 1999-06-26
CEN	EN 740	Anaesthetic workstations and their modules – Particular requirements	1998	C 227 of 1999-08-10
CEN	EN 793	Particular requirements for safety of medical supply units	1997	C 181 of 1999-06-26
CEN	EN 794-1	Lung ventilators - Part 1 : particular requirements for critical care ventilators	1997	C 181 of 1999-06-26
CEN	EN 794-2	Lung ventilators - Part 2 : particular requirements for home care use	1997	C 181 of 1999-06-26
CEN	EN 794-3	Medical electrical equipment - Lung ventilators - Part 3: Particular requirements for emergency and transport ventilators	1998	C 181 of 1999-06-26
CEN	EN 864	Medical electrical equipment : Capnometers for use with humans. Particular requirements	1996	C 181 of 1999-06-26
CEN	EN 865	Pulse oximeters - Particular requirements	1997	C 181 of 1999-06-26
CEN	EN 867-2	Non-biological systems for use in sterilizers - Part 2 : process indicators (class A)	1997	C 181 of 1999-06-26
CEN	EN 867-3	Non-biological systems for use in sterilizers - Part 3 : specification for class B indicators for use in the Bowie and Dick test	1997	C 181 of 1999-06-26
CEN	EN 868-1	Packaging materials and systems for medical devices which are to be sterilized -	1997	C 181 of 1999-06-26

		Part 1 : general requirements and test methods		
CEN	EN 980 A1	Graphical symbols for use in the labelling of medical devices	1996 1999	C 293 of 2000-10-14
CEN	EN 1041	Information supplied by the manufacturer with medical devices	1998	C 181 of 1999-06-26
CEN	EN 1060-1	Non-invasive sphygmomanometers - Part 1 : general requirement	1995	C 181 of 1999-06-26
CEN	EN 1060-2	Non-invasive sphygmomanometers - Part 2 : supplementary requirements for mechanical sphygmomanometers	1995	C 181 of 1999-06-26
CEN	EN 1060-3	Non-invasive sphygmomanometers - Part 3 : supplementary requirements for electromechanical blood pressure measuring systems	1997	C 181 of 1999-06-26
CEN	EN 1089-3	Transportable gas cylinders - Cylinder identification - Part 3 : colour coding	1997	C 181 of 1999-06-26
CEN	EN 1089-3/A1	Transportable Gas cylinders – Gas cylinder identification – Part 3: Colour coding	1997 1998	C 293 of 2000-10-14
CEN	EN 1174-1	Sterilization of medical devices - Estimation of the population of micro-organisms on product - Part 1: requirements	1996	C 181 of 1999-06-26
CEN	EN 1174-2	Sterilization of medical devices - Estimation of the population of micro-organisms on product - Part 2: guidance	1996	C 181 of 1999-06-26
CEN	EN 1174-3	Sterilization of medical devices - Estimation of the population of micro-organisms on product - Part 3: guide to the methods for validation of microbiological techniques	1996	C 181 of 1999-06-26
CEN	EN 1280-1	Agent specific filling systems for anaesthetic vaporizers - Part 1 : rectangular keyed filling systems	1997	C 181 of 1999-06-26
CEN	EN 1281-1	Anaesthetic and respiratory equipment - Conical connectors - Part 1 : cones and sockets	1997	C 181 of 1999-06-26
CEN	EN 1281-1 Amendment1	Anaesthetic and respiratory equipment - Conical connectors - Part 1 : cones and sockets	1997 1998	C 181 of 1999-06-26
CEN	EN 1281-2	Anaesthetic and respiratory equipment - Conical connectors - Part 2 : screw-threaded weight-bearing connectors (ISO 5356-2:1987 modified)	1995	C 181 of 1999-06-26
CEN	EN 1282-1	Anaesthetic and respiratory equipment - Tracheostomy tubes - Part 1 : tubes for use in adults	1996	C 181 of 1999-06-26
CEN	EN 1282-2	Tracheostomy tubes - Part 2 : paediatric tubes	1997	C 181 of 1999-06-26
CEN	EN 1422	Sterilisers for medical purposes – ethylene oxide sterilisers – requirements and test	1997	C 181 of 1999-06-26

		methods		
CEN	EN 1441	Medical devices – risk analysis	1997	C 181 of 1999-06-26
CEN	EN 1618	Catheters other than intravascular catheters – test methods for common properties	1997	C 181 of 1999-06-26
CEN	EN 1639	Dentistry - Medical devices for dentistry - Instruments	1996	C 181 of 1999-06-26
CEN	EN 1640	Dentistry - Medical devices for dentistry - Equipment	1996	C 181 of 1999-06-26
CEN	EN 1641	Dentistry - Medical devices for dentistry - Materials	1996	C 181 of 1999-06-26
CEN	EN 1642	Dentistry - Medical devices for dentistry - Dental implants	1996	C 181 of 1999-06-26
CEN	EN 1707	Conical fittings with a 6% (Luer) taper for syringes, needles and certain other medical equipment - Lock fittings	1996	C 181 of 1999-06-26
CEN	EN 1782	Tracheal tubes and connectors	1998	C 181 of 1999-06-26
CEN	EN 1819	Laryngoscopes for tracheal intubation – particular requirements	1997	C 181 of 1999-06-26
CEN	EN 1820	Anaesthetic reservoir bags	1997	C 181 of 1999-06-26
CEN	EN 1865	Specifications for stretchers and other patient handling equipment used in road ambulances	1999	C 293 of 2000-10-14
CEN	EN 1985	Walking aids - General requirements and test methods	1998	C 227 of 1999-08-10
CEN	EN ISO 4135	Anaesthesiology - Vocabulary (ISO 4135:1995)	1996	C 181 of 1999-06-26
CEN	EN ISO 8185	Humidifiers for medical use - General requirements for humidification systems	1997	C 181 of 1999-06-26
CEN	EN ISO 8359	Oxygen concentrators for medical use - Safety requirements	1996	C 181 of 1999-06-26
CEN	EN ISO 9703-3	Anaesthesia and respiratory care alarm signals - Part 3: Guidance on application of alarms (ISO 9703-3:1998)	1998	C 227 of 1999-08-10
CEN	EN ISO 10079-1	Medical suction equipment - Part 1 : electrically powered suction equipment - Safety requirements (ISO 10079-1:1991, including technical corrigendum 1:1992 and technical corrigendum 2:1993) Medical suction equipment – Part 1: Electrically powered suction equipment – Safety requirements (ISO 10079-1:1999)	1996 1999	C 181 of 1999-06-26 C 293 of 2000-10-14
CEN	EN ISO 10079-2	Medical suction equipment - Part 2 : manually powered suction equipment - (ISO 10079-2:1992)	1996	C 181 of 1999-06-26

		Medical suction equipment – Part 2: Manually powered suction equipment (ISO 10079-2:1999)	1999	C 293 of 2000-10-14
CEN	EN ISO 10079-3	Medical suction equipment - Part 3 : suction equipment powered from vacuum or pressure source (ISO 10079-3:1992) Medical suction equipment – Part 3: Suction equipment powered from a vacuum or pressure source (ISO 10079-3:1999)	1996 1999	C 181 of 1999-06-26 C 293 of 2000-10-14
CEN	EN ISO 10535	Hoists for the transfer of disabled persons - Requirements and test methods (ISO 10535:1998)	1998	C 293 of 2000-10-14
CEN	EN ISO 10555-1	Sterile, single-use intravascular catheters - Part 1 : general requirements (ISO 10555-1:1995)	1996	C 181 of 1999-06-26
CEN	EN ISO 10555-1/A1	Sterile, single-use intra-vascular catheters – Part 1: General requirements (ISO 10555-1:1996/Amd 1:1999)	1996 1999	C 293 of 2000-10-14
CEN	EN ISO 10993-1	Biological evaluation of medical devices - Part 1: Evaluation and testing (ISO 10993-1:1997)	1997	C 181 of 1999-06-26
CEN	EN ISO 10993-5	Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity (ISO 10993-5:1999)	1999	C 288 of 1999-10-09
CEN	EN ISO 10993-9	Biological evaluation of medical devices – Part 9: Framework for identification and quantification of potential degradation products (ISO 10993-9:1999)	1999	C 227 of 1999-08-12
CEN	EN ISO 10993-10	Biological evaluation of medical devices - Part 10 : tests for irritation and sensitisation (ISO 10993-10:1995)	1995	C 181 of 1999-06-26
CEN	EN ISO 10993-12	Biological evaluation of medical devices - Part 12 : sample preparation and reference materials (ISO 10993-12:1996)	1996	C 181 of 1999-06-26
CEN	EN ISO 10993-13	Biological evaluation of medical devices - Part 13: Identification and quantification of degradation products from polymeric medical devices (ISO 10993-13:1998)	1998	C 227 of 1999-08-12
CEN	EN ISO 10993-16	Biological evaluation of medical devices – Part 16: toxicokinetic study design for degradation products and leachables (ISO 10993-16:1997)	1997	C 181 of 1999-06-26
CEN	EN ISO 11196	Anaesthetic gas monitors (ISO 11196:1995 including technical corrigendum 1:1997)	1997	C 181 of 1999-06-26
CEN	EN ISO 11990	Optics and optical instruments – Lasers and laser-related equipment – Determination of laser resistance of tracheal tube shafts (ISO 11990:1999)	1999	C 293 of 2000-10-14

CEN	EN 12006-1	Non active surgical implants – Particular requirements for cardiac and vascular implants – Part 1: Heart valve substitutes	1999	C 293 of 2000-10-14
CEN	EN 12006-2	Non active surgical implants - Particular requirements for cardiac and vascular implants - Part 2: Vascular prostheses including cardiac valve conduits	1998	C 181 of 1999-06-26
CEN	EN 12006-3	Non active surgical implants - Particular requirements for cardiac and vascular implants - Part 3: Endovascular devices	1998	C 227 of 1999-08-10
CEN	EN 12010	Non active surgical implants - Joint replacement implants - Particular requirements	1998	C 181 of 1999-06-26
CEN	EN 12011	Instrumentation to be used in association with non-active surgical implants - General requirements	1998	C 181 of 1999-06-26
CEN	EN 12182	Technical aids for disabled persons – General requirements and test methods	1999	C 293 of 2000-10-14
CEN	EN 12183	Manually propelled wheelchairs – Requirements and test methods	1999	C 227 of 1999-08-10
CEN	EN 12184	Electrically powered wheelchairs, scooters and their chargers – Requirements and test methods	1999	C 227 of 1999-08-10
CEN	EN 12218	Rail systems for supporting medical equipment	1998	C 293 of 2000-10-14
CEN	EN 12342	Breathing tubes intended for use with anaesthetic apparatus and ventilators	1998	C 181 of 1999-06-26
CEN	EN 12470-1	Clinical thermometers – Part 1: Metallic liquid-in-glass thermometers with maximum device	2000	C 293 of 2000-10-14
CEN	EN 12470-3	Clinical thermometers – Part 3: Performance of compact electrical thermometers (non-predictive and predictive) with maximum device	2000	C 293 of 2000-10-14
CEN	EN 12523	External limb prostheses and external orthoses – Requirements and test methods	1998	C 227 of 1999-08-10
CEN	EN 12563	Non-active surgical implants - Joint replacement implants - Specific requirements for hip joint replacement implants	1998	C 227 of 1999-08-10
CEN	EN 12564	Non-active surgical implants - Joint replacement implants - Specific requirements for knee joint replacement implants	1998	C 227 of 1999-08-10
CEN	EN 12598	Oxygen monitors for patient breathing mixtures – Particular requirements	1999	C 227 of 1999-08-10
CEN	EN ISO 12870	Ophtalmic optics - Spectacle frames - General requirements and test methods	1997	C 181 of 1999-06-26
CEN	EN 13220	Flow-metering devices for connection to terminal units of medical gas pipeline	1998	C 293 of 2000-10-14

		systems		
CEN	EN ISO 14160	Sterilization of single-use medical devices incorporating materials of animal origin - Validation and routine control of sterilization by liquid chemical sterilants	1998	C 181 of 1999-06-26
CEN	EN ISO 14534	Ophthalmic optics - Contact lenses and contact lens care products - Fundamental requirements	1997	C 181 of 1999-06-26
CEN	EN ISO 14602	Non-active surgical implants - Implants for Osteosynthesis - Particular requirements	1998	C 181 of 1999-06-26
CEN	EN ISO 14630	Non-active surgical implants - General requirements	1997	C 181 of 1999-06-26
CEN	EN ISO 14889	Ophthalmic optics – spectacle lenses – fundamental requirements for uncut finished lenses (ISO 14889:1997)	1997	C 181 of 1999-06-26
CEN	EN ISO 15004	Ophthalmic instruments – fundamental requirements and test methods (ISO 594-1: 1986)	1997	C 181 of 1999-06-26
CEN	EN 20594-1	Conical fittings with a 6% (Luer) taper for syringes, needles and certain other medical equipment - Part 1 : General requirements (ISO 594-1:1986)	1993	C 181 of 1999-06-26
CEN	EN 20594-1 A1	Conical fittings with a 6% (Luer) taper for syringes, needles and certain other medical equipment - Part 1: General requirements (ISO 594-1:1986)	1993,1997	C 227 of 1999-08-10
CEN	EN 27740	Instruments for surgery, scalpels with detachable blades, fitting dimensions (ISO 7740:1985)	1992	C 181 of 1999-06-26
CEN	EN 27740 A1	Instruments for surgery, scalpels with detachable blades, fitting dimensions (ISO 7740:1985)	1992,1997	C 227 of 1999-08-10
CEN	EN 30993-3	Biological evaluation of medical devices - Part 3 : tests for genotoxicity, carcinogenicity and reproductive toxicity (ISO 10993-3:1992)	1993	C 181 of 1999-06-26
CEN	EN 30993-4	Biological evaluation of medical devices - Part 4 : selection of tests for interactions with blood (ISO 10993-4:1992)	1993	C 181 of 1999-06-26
CEN	EN 30993-5	Biological evaluation of medical devices - Part 5 : tests for cytotoxicity - in vitro methods (ISO 10993-5:1992)	1993	C 181 of 1999-06-26
CEN	EN 30993-6	Biological evaluation of medical devices - Part 6: Tests for local effects after implantation (ISO 10993-6:1994)	1994	C 181 of 1999-06-26
CEN	EN 30993-7	Biological evaluation of medical devices - Part 7: ethylene oxide sterilisation residuals (ISO 10993-7:1995)	1995	C 293 of 2000-10-14
CEN	EN 30993-11	Biological evaluation of medical devices - Part 11: tests for systemic toxicity (ISO 10993-11:1993)	1995	C 181 of 1999-06-26

CEN/ CENELEC	EN 46001	Quality systems - Medical devices - Particular requirements for the application of EN ISO 9001	1995	C 181 of 1999-06-26
CEN/ CENELEC	EN 46002	Quality systems - Medical devices - Particular requirements for the application of EN ISO 9002	1995	C 181 of 1999-06-26
CEN/ CENELEC	EN 46003	Quality systems - Medical devices - Particular requirements for the application of EN ISO 9003	1999	C 293 of 2000-10-14
CENELEC	EN 50103	Guidance on the application of EN 29001 and EN 46001 and of EN 29002 and EN 46002 for the active (including active implantable) medical device industry	1994	C 181 of 1999-06-26
CENELEC	EN 60601-1	Medical electrical equipment. Part 1: General requirements for safety - IEC 601-1:1988	1990	C 181 of 1999-06-26
CENELEC	Amendment A1 to EN 60601-1	Medical electrical equipment. Part 1: General requirements for safety - IEC 601-1:1988/A1:1991	1992	C 181 of 1999-06-26
CENELEC	Amendment A2 to EN 60601-1	Medical electrical equipment. Part 1: General requirements for safety - IEC 601-1:1988/A2:1995 + corrigendum June 1995	1995	C 181 of 1999-06-26
CENELEC	Amendment A13 to EN 60601-1	Medical electrical equipment. Part 1: General requirements for safety	1995	C 181 of 1999-06-26
CENELEC	EN 60601-1-1	Medical electrical equipment. Part 1: General requirements for safety - 1. Collateral standard: Safety requirements for medical electrical systems - IEC 601-1-1:1992	1993	C 181 of 1999-06-26
CENELEC	Amendment A1 to EN 60601-1-1	Medical electrical equipment . Part 1: General requirements for safety - 1. Collateral standard: Safety requirements for medical electrical systems IEC 601-1-1:1992/A1:1995	1995	C 181 of 1999-06-26
CENELEC	EN 60601-1-2	Medical electrical equipment - Part 1: General requirements for safety - 2. Collateral standard: Electromagnetic compatibility - Requirements and tests IEC 601-1-2: 1993	1993	C 181 of 1999-06-26
CENELEC	EN 60601-1-3	Medical electrical equipment. Part 1: General requirements for safety - 3: Collateral standard: General requirements for radiation protection in diagnostic X-ray equipment. IEC 601-1-3:1994	1994	C 181 of 1999-06-26
CENELEC	EN 60601-1-4	Medical electrical equipment - Part 1: General requirements for safety - 4. Collateral standard: Programmable electrical medical systems - IEC 60601-1-4:1996	1996	C 181 of 1999-06-26
CENELEC	EN 60601-2-2	Medical electrical equipment. Part 2: Particular requirements for the safety of high frequency surgical equipment - IEC 601-2-2:1991	1992	C 181 of 1999-06-26

CENELEC	EN 60601-2-3	Medical electrical equipment. Part 2: Particular requirements for the safety of short-wave therapy equipment - IEC 601-2-3:1991	1992	C 181 of 1999-06-26
CENELEC	EN 60601-2-7	Medical electrical equipment -- Part 2-7: Particular requirements for the safety of high-voltage generators of diagnostic X-ray generators (IEC 60601-2-7:1998) Amendment A1:1997 to EN 60601-2-8:1997 (IEC 60601-2-8:1987 /A1:1997)	1998	C 288 of 1999-10-09
CENELEC	EN 60601-2-9	Medical electrical equipment -- Part 2: Particular requirements for the safety of patient contact dosemeters used in radiotherapy with electrically connected radiation detectors (IEC 60601-2-9:1996)	1996	C 288 of 1999-10-09
CENELEC	EN 60601-2-11	Medical electrical equipment -- Part 2: Particular requirements for the safety of gamma beam therapy equipment (IEC 60601-2-11:1997)	1997	C 288 of 1999-10-09
CENELEC	EN 60601-2-16	Medical electrical equipment -- Part 2-16: Particular requirements for the safety of haemodialysis, haemodiafiltration an haemofiltration equipment (IEC 60601-2-16: 1998)	1998	C 288 of 1999-10-09
CENELEC	EN 60601-2-17	Medical electrical equipment. Part 2: Particular requirements for the safety of remote-controlled automatically-driven gamma-ray after-loading equipment IEC 601-2-17:1989	1996	C 181 of 1999-06-26
CENELEC	Amendment A1 to EN 60601-2-17	Medical electrical equipment. Part 2: Particular requirements for the safety of remote-controlled automatically-driven gamma-ray after-loading equipment. IEC 601-2-17:1989/A1:1996	1996	C 181 of 1999-06-26
CENELEC	EN 60601-2-18	Medical electrical equipment -- Part 2: Particular requirements for the safety of endoscopic equipment (IEC 60601-2-18:1996)	1996	C 288 of 1999-10-09
CENELEC	EN 60601-2-19	Medical electrical equipment -- Part 2: Particular requirements for the safety of baby incubators (IEC 60601-2-19:1990) Amendment A1:1996 to EN 60601-2-19:1996 (IEC 60601-2-19:1990/A1:1996)	1996	C 288 of 1999-10-09
CENELEC	EN 60601-2-20	Medical electrical equipment -- Part 2: Particular requirements for the safety of transport incubators (IEC 60601-2-20:1990 + A1:1996)	1996	C 288 of 1999-10-09

CENELEC	EN 60601-2-21	Medical electrical equipment -- Part 2: Particular requirements for the safety of infant radiant warmers (IEC 601-2-21:1994) Amendment A1:1996 to EN 60601-2-21:1994 (IEC 60601-2-21:1994/A1:1996)	1994	C 288 of 1999-10-09
CENELEC	EN 60601-2-22	Medical electrical equipment . Part 2: Particular requirements for the safety of diagnostic and therapeutic laser equipment. IEC 601-2-22:1995	1995	C 181 of 1999-06-26
CENELEC	EN 60601-2-23	Medical electrical equipment -- Part 2: Particular requirements for the safety of transcutaneous partial pressure monitoring equipment (IEC 60601-2-23:1993)	1997	C 288 of 1999-10-09
CENELEC	EN 60601-2-24	Medical electrical equipment -- Part 2: Particular requirements for the safety of infusion pumps and controllers (IEC 60601-2-24:1998)	1998	C 288 of 1999-10-09
CENELEC	EN 60601-2-25	Medical electrical equipment. Part 2: Particular requirements for the safety of electrocardiographs. IEC 601-2-25:1993	1995	C 181 of 1999-06-26
CENELEC	EN 60601-2-26	Medical electrical equipment. Part 2: Particular requirements for the safety of electroencephalographs. IEC 601-2-26:1994	1994	C 181 of 1999-06-26
CENELEC	EN 60601-2-27	Medical electrical equipment. Part 2: Particular requirements for the safety of electrocardiographic monitoring equipment - IEC 601-2-27:1994	1994	C 181 of 1999-06-26
CENELEC	EN 60601-2-28	Medical electrical equipment. Part 2: Particular requirements for the safety of X-ray source assemblies and X-ray tube assemblies for medical diagnosis. IEC 601-2-28:1993	1993	C 181 of 1999-06-26
CENELEC	EN 60601-2-29	Medical electrical equipment -- Part 2: Particular requirements for the safety of radiotherapy simulators (IEC 60601-2-29:1993) Amendment A1:1996 to EN 60601-2-29:1995 (IEC60601-2-29:1993/A1:1996)	1995	C 288 of 1999-10-09
CENELEC	EN 60601-2-30	Medical electrical equipment. Part 2: Particular requirements for the safety of automatic cycling indirect blood pressure monitoring equipment . IEC 601-2-30:1995	1995	C 181 of 1999-06-26
CENELEC	EN 60601-2-31	Medical electrical equipment. Part 2: Particular requirements for the safety of external cardiac pacemakers with internal power source. IEC 601-2-31:1994	1994	C 181 of 1999-06-26
CENELEC	EN 60601-2-	Medical electrical equipment. Part 2:	1994	C 181 of

	32	Particular requirements for the safety of associated equipment of X-ray equipment - IEC 601-2-32:1994		1999-06-26
CENELEC	EN 60601-2-33	Medical electrical equipment. Part 2: Particular requirements for the safety of magnetic resonance equipment for medical diagnosis. IEC 601-2-33:1995	1995	C 181 of 1999-06-26
CENELEC	EN 60601-2-34	Medical electrical equipment. Part 2: Particular requirements for the safety of direct blood-pressure monitoring equipment - IEC 601-2-34:1994	1995	C 181 of 1999-06-26
CENELEC	EN 60601-2-35	Medical electrical equipment -- Part 2: Particular requirements for the safety of blankets, pads and mattresses, intended for heating in medical use (IEC 60601-2-35:1996)	1996	C 288 of 1999-10-09
CENELEC	EN 60601-2-36	Medical electrical equipment -- Part 2: Particular requirements for the safety of equipment for extracorporeally induced lithotripsy (IEC 60601-2-36:1997)	1997	C 288 of 1999-10-09
CENELEC	EN 60601-2-38	Medical electrical equipment -- Part 2-38: Particular requirements for the safety of electrically operated hospital beds (IEC 60601-2-38:1996)	1996	C 288 of 1999-10-09
CENELEC	EN 60601-2-40	Medical electrical equipment -- Part 2-40: Particular requirements for the safety of electromyographs and evoked response equipment (IEC 60601-2-40:1998)	1998	C 288 of 1999-10-09
CENELEC	EN 60645-1	Audiometers. Part 1 : pure-tone audiometers - IEC 645-1:1992 + corrigendum Feb. 1993	1994	C 181 of 1999-06-26
CENELEC	EN 60645-2	Audiometers. Part 2: Equipment for speech audiometry. IEC 645-2:1993	1996	C 181 of 1999-06-26
CENELEC	EN 60645-3	Audiometers. Part 3 : auditory test signals of short duration for audiometric and neuro-otological purposes - IEC 645-3:1994	1994	C 181 of 1999-06-26
CENELEC	EN 60645-4	Audiometers. Part 4 : equipment for extended high-frequency audiometry. IEC 645-4:1994	1994	C 181 of 1999-06-26