Commission communication in the framework of the implementation of the Council Directive 93/42/EEC concerning medical devices

(Publication of titles and references of harmonised standards under Union harmonisation legislation)

(Text with EEA relevance)

(2017/C 389/03)

ESO ([1])	Reference and title of the standard (and reference document)	First publication OJ	Reference of superseded standard	Date of cessation of presumption of conformity of superseded standard Note 1
(1)	(2)	(3)	(4)	(5)
CEN	EN 285:2006+A2:2009 Sterilization — Steam sterilizers — Large sterilizers	2.12.2009	EN 285:2006+A1:2008 Note 2.1	21.3.2010
CEN	EN 455-1:2000 Medical gloves for single use — Part 1: Requirements and testing for freedom from holes	30.9.2005	EN 455-1:1993 Note 2.1	30.4.2001
CEN	EN 455-2:2009+A2:2013 Medical gloves for single use — Part 2: Requirements and testing for physical properties	16.5.2014	EN 455-2:2009 +A1:2011 Note 2.1	31.10.2014
CEN	EN 455-3:2006 Medical gloves for single use — Part 3: Requirements and testing for biological evaluation	9.8.2007	EN 455-3:1999 Note 2.1	30.6.2007
CEN	EN 455-4:2009 Medical gloves for single use — Part 4: Requirements and testing for shelf life determination	7.7.2010		
CEN	EN 556-1:2001 Sterilization of medical devices — Requirements for medical devices to be designated 'STERILE' — Part 1: Requirements for terminally sterilized medical devices	31.7.2002	EN 556:1994 + A1:1998 Note 2.1	30.4.2002
	EN 556-1:2001/AC:2006	15.11.2006		
CEN	EN 556-2:2015 Sterilization of medical devices — Requirements for medical devices to be designated 'STERILE' — Part 2: Requirements for aseptically processed medical devices	13.5.2016	EN 556-2:2003 Note 2.1	30.6.2016

(1)	(2)	(3)	(4)	(5)
CEN	EN 794-3:1998+A2:2009 Lung ventilators — Part 3: Particular requirements for emergency and transport ventilators	7.7.2010	EN 794-3:1998 Note 2.1	21.3.2010
CEN	EN 1041:2008 Information supplied by the manufacturer of medical devices	19.2.2009	EN 1041:1998 Note 2.1	31.8.2011
CEN	EN 1060-3:1997+A2:2009 Non-invasive sphygmomanometers — Part 3: Supplementary requirements for electro-mechanical blood pressure measuring systems	7.7.2010	EN 1060-3:1997 Note 2.1	31.5.2010
CEN	EN 1060-4:2004 Non-invasive sphygmomanometers — Part 4: Test procedures to determine the overall system accuracy of automated non-invasive sphygmomanometers	30.9.2005		
CEN	EN ISO 1135-4:2011 Transfusion equipment for medical use — Part 4: Transfusion sets for single use (ISO 1135-4:2010)	27.4.2012	EN ISO 1135-4:2010 Note 2.1	30.4.2012
CEN	EN 1282-2:2005+A1:2009 Tracheostomy tubes — Part 2: Paediatric tubes (ISO 5366-3:2001, modified)	7.7.2010	EN 1282-2:2005 Note 2.1	21.3.2010
CEN	EN 1422:1997+A1:2009 Sterilizers for medical purposes — Ethylene oxide sterilizers — Requirements and test methods	2.12.2009	EN 1422:1997 Note 2.1	21.3.2010
CEN	EN 1618:1997 Catheters other than intravascular catheters — Test methods for common properties	9.5.1998		
CEN	EN 1639:2009 Dentistry — Medical devices for dentistry — Instruments	7.7.2010	EN 1639:2004 Note 2.1	30.4.2010
CEN	EN 1640:2009 Dentistry — Medical devices for dentistry — Equipment	7.7.2010	EN 1640:2004 Note 2.1	30.4.2010
CEN	EN 1641:2009 Dentistry — Medical devices for dentistry — Materials	7.7.2010	EN 1641:2004 Note 2.1	30.4.2010
CEN	EN 1642:2011 Dentistry — Medical devices for dentistry — Dental implants	27.4.2012	EN 1642:2009 Note 2.1	30.4.2012

(1)	(2)	(3)	(4)	(5)
CEN	EN 1707:1996 Conical fittings with a 6 % (Luer) taper for syringes, needles and certain other medical equipment — Lock fittings	17.5.1997		
CEN	EN 1782:1998+A1:2009 Tracheal tubes and connectors	7.7.2010	EN 1782:1998 Note 2.1	21.3.2010
CEN	EN 1789:2007+A1:2010 Medical vehicles and their equipment — Road ambulances	18.1.2011		
CEN	EN 1820:2005+A1:2009 Anaesthetic reservoir bags (ISO 5362:2000, modified)	7.7.2010	EN 1820:2005 Note 2.1	21.3.2010
CEN	EN 1865-1:2010+A1:2015 Patient handling equipment used in road ambulances — Part 1: General stretcher systems and patient handling equipment	13.5.2016		
CEN	EN 1865-2:2010+A1:2015 Patient handling equipment used in road ambulances — Part 2: Power assisted stretcher	13.5.2016		
CEN	EN 1865-3:2012 Patient handling equipment used in road ambulances — Part 3: Heavy duty stretcher	30.8.2012	EN 1865:1999 Note 2.1	31.12.2012
CEN	EN 1865-4:2012 Patient handling equipment used in road ambulances — Part 4: Foldable patient transfer chair	30.8.2012	EN 1865:1999 Note 2.1	31.10.2012
CEN	EN 1865-5:2012 Patient handling equipment used in road ambulances — Part 5: Stretcher support	30.8.2012	EN 1865:1999 Note 2.1	31.12.2012
CEN	EN 1985:1998 Walking aids — General requirements and test methods	10.8.1999		

This standard still needs to be amended to take into account the requirements introduced by Directive 2007/47/EC. The amended standard will be published by CEN as soon as possible. Manufacturers are advised to check whether all relevant Essential Requirements of the amended directive are appropriately covered.

CEN	EN ISO 3826-2:2008 Plastics collapsible containers for human blood and blood components — Part 2: Graphical symbols for use on labels and instruction leaflets (ISO 3826-2:2008)	19.2.2009		
CEN	EN ISO 3826-3:2007 Plastics collapsible containers for human blood and blood components — Part 3: Blood bag systems with integrated features (ISO 3826-3:2006)	27.2.2008		

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CEN	EN ISO 3826-4:2015 Plastics collapsible containers for human blood and blood components — Part 4: Aphaeresis blood bag systems with integrated features (ISO 3826-4:2015)	13.5.2016		
CEN	EN ISO 4074:2002 Natural latex rubber condoms — Requirements and test methods (ISO 4074:2002)	31.7.2002	EN 600:1996 Note 2.1	31.8.2005
CEN	EN ISO 4135:2001 Anaesthetic and respiratory equipment — Vocabulary (ISO 4135:2001)	31.7.2002	EN ISO 4135:1996 Note 2.1	28.2.2002
CEN	EN ISO 5359:2008 Low-pressure hose assemblies for use with medical gases (ISO 5359:2008)	23.7.2008	EN 739:1998 Note 2.1	30.6.2010
	EN ISO 5359:2008/A1:2011	30.8.2012	Note 3	30.6.2012
CEN	EN ISO 5360:2009 Anaesthetic vaporizers — Agent-specific filling systems (ISO 5360:2006)	2.12.2009	EN ISO 5360:2007 Note 2.1	21.3.2010
CEN	EN ISO 5366-1:2009 Anaesthetic and respiratory equipment — Tracheostomy tubes — Part 1: Tubes and connectors for use in adults (ISO 5366-1:2000)	2.12.2009	EN ISO 5366-1:2004 Note 2.1	21.3.2010
CEN	EN ISO 5840:2009 Cardiovascular implants — Cardiac valve prostheses (ISO 5840:2005)	2.12.2009	EN ISO 5840:2005 Note 2.1	21.3.2010
CEN	EN ISO 7197:2009 Neurosurgical implants — Sterile, single-use hydrocephalus shunts and components (ISO 7197:2006, including Cor 1:2007)	2.12.2009	EN ISO 7197:2006 Note 2.1	21.3.2010
CEN	EN ISO 7376:2009 Anaesthetic and respiratory equipment — Laryngoscopes for tracheal intubation (ISO 7376:2009)	2.12.2009	EN ISO 7376:2009 Note 2.1	21.3.2010
CEN	EN ISO 7396-1:2007 Medical gas pipeline systems — Part 1: Pipeline systems for compressed medical gases and vacuum (ISO 7396-1:2007)	9.8.2007	EN 737-3:1998 Note 2.1	30.4.2009
	EN ISO 7396-1:2007/A1:2010	7.7.2010	Note 3	31.7.2010

(1)	(2)	(3)	(4)	(5)
	EN ISO 7396-1:2007/A2:2010	7.7.2010	Note 3	31.8.2010
CEN	EN ISO 7396-2:2007 Medical gas pipeline systems — Part 2: Anaesthetic gas scavenging disposal systems (ISO 7396-2:2007)	9.8.2007	EN 737-2:1998 Note 2.1	30.4.2009
CEN	EN ISO 7886-3:2009 Sterile hypodermic syringes for single use — Part 3: Auto-disable syringes for fixed-dose immunization (ISO 7886-3:2005)	7.7.2010	EN ISO 7886-3:2005 Note 2.1	21.3.2010
CEN	EN ISO 7886-4:2009 Sterile hypodermic syringes for single use — Part 4: Syringes with reuse prevention feature (ISO 7886-4:2006)	7.7.2010	EN ISO 7886-4:2006 Note 2.1	21.3.2010
CEN	EN ISO 8185:2009 Respiratory tract humidifiers for medical use — Particular requirements for respiratory humidification systems (ISO 8185:2007)	2.12.2009	EN ISO 8185:2007 Note 2.1	21.3.2010
CEN	EN ISO 8359:2009 Oxygen concentrators for medical use — Safety requirements (ISO 8359:1996)	2.12.2009	EN ISO 8359:1996 Note 2.1	21.3.2010
	EN ISO 8359:2009/A1:2012	16.1.2015	Note 3	31.1.2013
CEN	EN ISO 8835-2:2009 Inhalational anaesthesia systems — Part 2: Anaesthetic breathing systems (ISO 8835-2:2007)	2.12.2009	EN ISO 8835-2:2007 Note 2.1	21.3.2010
CEN	EN ISO 8835-3:2009 Inhalational anaesthesia systems — Part 3: Transfer and receiving systems of active anaesthetic gas scavenging systems (ISO 8835-3:2007)	2.12.2009	EN ISO 8835-3:2007 Note 2.1	21.3.2010
	EN ISO 8835-3:2009/A1:2010	13.5.2011	Note 3	30.4.2011
CEN	EN ISO 8835-4:2009 Inhalational anaesthesia systems — Part 4: Anaesthetic vapour delivery devices (ISO 8835-4:2004)	2.12.2009	EN ISO 8835-4:2004 Note 2.1	21.3.2010
CEN	EN ISO 8835-5:2009 Inhalational anaesthesia systems — Part 5: Anaesthetic ventilators (ISO 8835-5:2004)	2.12.2009	EN ISO 8835-5:2004 Note 2.1	21.3.2010

(1)	(2)	(3)	(4)	(5)
CEN	EN ISO 9170-1:2008 Terminal units for medical gas pipeline systems — Part 1: Terminal units for use with compressed medical gases and vacuum (ISO 9170-1:2008)	19.2.2009	EN 737-1:1998 Note 2.1	31.7.2010
CEN	EN ISO 9170-2:2008 Terminal units for medical gas pipeline systems — Part 2: Terminal units for anaesthetic gas scavenging systems (ISO 9170-2:2008)	19.2.2009	EN 737-4:1998 Note 2.1	31.7.2010
CEN	EN ISO 9360-1:2009 Anaesthetic and respiratory equipment — Heat and moisture exchangers (HMEs) for humidifying respired gases in humans — Part 1: HMEs for use with minimum tidal volumes of 250 ml (ISO 9360-1:2000)	2.12.2009	EN ISO 9360-1:2000 Note 2.1	21.3.2010
CEN	EN ISO 9360-2:2009 Anaesthetic and respiratory equipment — Heat and moisture exchangers (HMEs) for humidifying respired gases in humans — Part 2: HMEs for use with tracheostomized patients having minimum tidal volumes of 250 ml (ISO 9360-2:2001)	2.12.2009	EN ISO 9360-2:2002 Note 2.1	21.3.2010
CEN	EN ISO 9713:2009 Neurosurgical implants — Self-closing intracranial aneurysm clips (ISO 9713:2002)	2.12.2009	EN ISO 9713:2004 Note 2.1	21.3.2010
CEN	EN ISO 10079-1:2009 Medical suction equipment — Part 1: Electrically powered suction equipment — Safety requirements (ISO 10079-1:1999)	2.12.2009	EN ISO 10079-1:1999 Note 2.1	21.3.2010
CEN	EN ISO 10079-2:2009 Medical suction equipment — Part 2: Manually powered suction equipment (ISO 10079-2:1999)	2.12.2009	EN ISO 10079-2:1999 Note 2.1	21.3.2010
CEN	EN ISO 10079-3:2009 Medical suction equipment — Part 3: Suction equipment powered from a vacuum or pressure source (ISO 10079-3:1999)	2.12.2009	EN ISO 10079-3:1999 Note 2.1	21.3.2010
CEN	EN ISO 10328:2016 Prosthetics — Structural testing of lower-limb prostheses — Requirements and test methods (ISO 10328:2016)	This is the first publication	EN ISO 10328:2006 Note 2.1	30.6.2018

(1)	(2)	(3)	(4)	(5)
CEN	EN ISO 10524-1:2006 Pressure regulators for use with medical gases — Part 1: Pressure regulators and pressure regulators with flow-metering devices (ISO 10524-1:2006)	2.6.2006	EN 738-1:1997 Note 2.1	31.10.2008
CEN	EN ISO 10524-2:2006 Pressure regulators for use with medical gases — Part 2: Manifold and line pressure regulators (ISO 10524-2:2005)	7.6.2009	EN 738-2:1998 Note 2.1	31.10.2008
CEN	EN ISO 10524-3:2006 Pressure regulators for use with medical gases — Part 3: Pressure regulators integrated with cylinder valves (ISO 10524-3:2005)	7.9.2006	EN 738-3:1998 Note 2.1	31.10.2008
CEN	EN ISO 10524-4:2008 Pressure regulators for use with medical gases — Part 4: Low-pressure regulators (ISO 10524-4:2008)	23.7.2008	EN 738-4:1998 Note 2.1	30.6.2010
CEN	EN ISO 10535:2006 Hoists for the transfer of disabled persons — Requirements and test methods (ISO 10535:2006)	9.8.2007	EN ISO 10535:1998 Note 2.1	30.6.2007

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CEN	EN ISO 10555-1:2009 Sterile, single-use intravascular catheters — Part 1: General requirements (ISO 10555-1:1995, including Amd 1:1999 and Amd 2:2004)	2.12.2009	EN ISO 10555-1:1996 Note 2.1	21.3.2010
CEN	EN ISO 10651-2:2009 Lung ventilators for medical use — Particular requirements for basic safety and essential performance — Part 2: Home care ventilators for ventilator-dependent patients (ISO 10651-2:2004)	2.12.2009	EN ISO 10651-2:2004 Note 2.1	21.3.2010
CEN	EN ISO 10651-4:2009 Lung ventilators — Part 4: Particular requirements for operator-powered resuscitators (ISO 10651-4:2002)	2.12.2009	EN ISO 10651-4:2002 Note 2.1	21.3.2010
CEN	EN ISO 10651-6:2009 Lung ventilators for medical use — Particular requirements for basic safety and essential performance — Part 6: Home-care ventilatory support devices (ISO 10651-6:2004)	2.12.2009	EN ISO 10651-6:2004 Note 2.1	21.3.2010

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CEN	EN ISO 10993-1:2009 Biological evaluation of medical devices — Part 1: Evaluation and testing within a risk management process (ISO 10993-1:2009)	2.12.2009	EN ISO 10993-1:2009 Note 2.1	21.3.2010
	EN ISO 10993-1:2009/AC:2010	18.1.2011		
CEN	EN ISO 10993-3:2014 Biological evaluation of medical devices — Part 3: Tests for genotoxicity, carcinogenicity and reproductive toxicity (ISO 10993-3:2014)	10.7.2015	EN ISO 10993-3:2009 Note 2.1	The date of this publication
CEN	EN ISO 10993-4:2009 Biological evaluation of medical devices — Part 4: Selection of tests for interactions with blood (ISO 10993-4:2002, including Amd 1:2006)	2.12.2009	EN ISO 10993-4:2002 Note 2.1	21.3.2010
CEN	EN ISO 10993-5:2009 Biological evaluation of medical devices — Part 5: Tests for in vitro cytotoxicity (ISO 10993-5:2009)	2.12.2009	EN ISO 10993-5:1999 Note 2.1	31.12.2009
CEN	EN ISO 10993-6:2009 Biological evaluation of medical devices — Part 6: Tests for local effects after implantation (ISO 10993-6:2007)	2.12.2009	EN ISO 10993-6:2007 Note 2.1	21.3.2010
CEN	EN ISO 10993-7:2008 Biological evaluation of medical devices — Part 7: Ethylene oxide sterilization residuals (ISO 10993-7:2008)	19.2.2009		
	EN ISO 10993-7:2008/AC:2009	7.7.2010		
CEN	EN ISO 10993-9:2009 Biological evaluation of medical devices — Part 9: Framework for identification and quantification of potential degradation products (ISO 10993-9:2009)	2.12.2009	EN ISO 10993-9:2009 Note 2.1	21.3.2010
CEN	EN ISO 10993-11:2009 Biological evaluation of medical devices — Part 11: Tests for systemic toxicity (ISO 10993-11:2006)	2.12.2009	EN ISO 10993-11:2006 Note 2.1	21.3.2010
CEN	EN ISO 10993-12:2012 Biological evaluation of medical devices — Part 12: Sample preparation and reference materials (ISO 10993-12:2012)	24.1.2013	EN ISO 10993-12:2009 Note 2.1	31.1.2013

(1)	(2)	(3)	(4)	(5)
CEN	EN ISO 10993-13:2010 Biological evaluation of medical devices — Part 13: Identification and quantification of degradation products from polymeric medical devices (ISO 10993-13:2010)	18.1.2011	EN ISO 10993-13:2009 Note 2.1	31.12.2010
CEN	EN ISO 10993-14:2009 Biological evaluation of medical devices — Part 14: Identification and quantification of degradation products from ceramics (ISO 10993-14:2001)	2.12.2009	EN ISO 10993-14:2001 Note 2.1	21.3.2010
CEN	EN ISO 10993-15:2009 Biological evaluation of medical devices — Part 15: Identification and quantification of degradation products from metals and alloys (ISO 10993-15:2000)	2.12.2009	EN ISO 10993-15:2000 Note 2.1	21.3.2010
CEN	EN ISO 10993-16:2010 Biological evaluation of medical devices — Part 16: Toxicokinetic study design for degradation products and leachables (ISO 10993-16:2010)	7.7.2010	EN ISO 10993-16:2009 Note 2.1	31.8.2010
CEN	EN ISO 10993-17:2009 Biological evaluation of medical devices — Part 17: Establishment of allowable limits for leachable substances (ISO 10993-17:2002)	2.12.2009	EN ISO 10993-17:2002 Note 2.1	21.3.2010
CEN	EN ISO 10993-18:2009 Biological evaluation of medical devices — Part 18: Chemical characterization of materials (ISO 10993-18:2005)	2.12.2009	EN ISO 10993-18:2005 Note 2.1	21.3.2010
CEN	EN ISO 11135-1:2007 Sterilization of health care products — Ethylene oxide — Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices (ISO 11135-1:2007)	9.8.2007	EN 550:1994 Note 2.1	31.5.2010
CEN	EN ISO 11137-1:2015 Sterilization of health care products — Radiation — Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices (ISO 11137-1:2006, including Amd 1:2013)	13.5.2016	EN ISO 11137-1:2006 Note 2.1	30.6.2016
CEN	EN ISO 11137-2:2015 Sterilization of health care products — Radiation — Part 2: Establishing the sterilization dose (ISO 11137-2:2013)	13.5.2016	EN ISO 11137-2:2013 Note 2.1	30.6.2016

(1)	(2)	(3)	(4)	(5)
CEN	EN ISO 11138-2:2009 Sterilization of health care products — Biological indicators — Part 2: Biological indicators for ethylene oxide sterilization processes (ISO 11138-2:2006)	2.12.2009	EN ISO 11138-2:2006 Note 2.1	21.3.2010
CEN	EN ISO 11138-3:2009 Sterilization of health care products — Biological indicators — Part 3: Biological indicators for moist heat sterilization processes (ISO 11138-3:2006)	2.12.2009	EN ISO 11138-3:2006 Note 2.1	21.3.2010
CEN	EN ISO 11140-1:2009 Sterilization of health care products — Chemical indicators — Part 1: General requirements (ISO 11140-1:2005)	2.12.2009	EN ISO 11140-1:2005 Note 2.1	21.3.2010
CEN	EN ISO 11140-3:2009 Sterilization of health care products — Chemical indicators — Part 3: Class 2 indicator systems for use in the Bowie and Dick-type steam penetration test (ISO 11140-3:2007, including Cor 1:2007)	2.12.2009	EN ISO 11140-3:2007 Note 2.1	21.3.2010
CEN	EN ISO 11197:2009 Medical supply units (ISO 11197:2004)	2.12.2009	EN ISO 11197:2004 Note 2.1	21.3.2010
CEN	EN ISO 11607-1:2009 Packaging for terminally sterilized medical devices — Part 1: Requirements for materials, sterile barrier systems and packaging systems (ISO 11607-1:2006)	2.12.2009	EN ISO 11607-1:2006 Note 2.1	21.3.2010
CEN	EN ISO 11607-2:2006 Packaging for terminally sterilized medical devices — Part 2: Validation requirements for forming, sealing and assembly processes (ISO 11607-2:2006)	7.9.2006		
CEN	EN ISO 11737-1:2006 Sterilization of medical devices — Microbiological methods — Part 1: Determination of a population of microorganisms on products (ISO 11737-1:2006)	7.9.2006	EN 1174-1:1996 EN 1174-2:1996 EN 1174-3:1996 Note 2.1	31.10.2006
	EN ISO 11737-1:2006/AC:2009	2.12.2009		
CEN	EN ISO 11737-2:2009 Sterilization of medical devices — Microbiological methods — Part 2: Tests of sterility performed in the definition, validation and maintenance of a sterilization process (ISO 11737-2:2009)	7.7.2010		

(1)	(2)	(3)	(4)	(5)
CEN	EN ISO 11810-1:2009 Lasers and laser-related equipment — Test method and classification for the laser resistance of surgical drapes and/or patient protective covers — Part 1: Primary ignition and penetration (ISO 11810-1:2005)	2.12.2009		
CEN	EN ISO 11810-2:2009 Lasers and laser-related equipment — Test method and classification for the laser-resistance of surgical drapes and/or patient-protective covers — Part 2: Secondary ignition (ISO 11810-2:2007)	2.12.2009	EN ISO 11810-2:2007 Note 2.1	21.3.2010
CEN	EN ISO 11979-8:2009 Ophthalmic implants — Intraocular lenses — Part 8: Fundamental requirements (ISO 11979-8:2006)	2.12.2009	EN ISO 11979-8:2006 Note 2.1	21.3.2010
CEN	EN ISO 11990-1:2014 Lasers and laser-related equipment — Determination of laser resistance of tracheal tubes — Part 1: Tracheal tube shaft (ISO 11990-1:2011)	10.7.2015		
CEN	EN ISO 11990-2:2014 Lasers and laser-related equipment — Determination of laser resistance of tracheal tubes — Part 2: Tracheal tube cuffs (ISO 11990-2:2010)	10.7.2015		
CEN	EN 12006-2:1998+A1:2009 Non active surgical implants — Particular requirements for cardiac and vascular implants — Part 2: Vascular prostheses including cardiac valve conduits	2.12.2009	EN 12006-2:1998 Note 2.1	21.3.2010
CEN	EN 12006-3:1998+A1:2009 Non active surgical implants — Particular requirements for cardiac and vascular implants — Part 3: Endovascular devices	2.12.2009	EN 12006-3:1998 Note 2.1	21.3.2010
CEN	EN 12183:2009 Manual wheelchairs — Requirements and test methods	7.7.2010		
CEN	EN 12184:2009 Electrically powered wheelchairs, scooters and their chargers — Requirements and test methods	7.7.2010		
CEN	EN 12342:1998+A1:2009 Breathing tubes intended for use with anaesthetic apparatus and ventilators	7.7.2010	EN 12342:1998 Note 2.1	21.3.2010

(1)	(2)	(3)	(4)	(5)
CEN	EN 12470-1:2000+A1:2009 Clinical thermometers — Part 1: Metallic liquid-in-glass thermometers with maximum device	2.12.2009	EN 12470-1:2000 Note 2.1	21.3.2010
CEN	EN 12470-2:2000+A1:2009 Clinical thermometers — Part 2: Phase change type (dot matrix) thermometers	2.12.2009	EN 12470-2:2000 Note 2.1	21.3.2010
CEN	EN 12470-3:2000+A1:2009 Clinical thermometers — Part 3: Performance of compact electrical thermometers (non-predictive and predictive) with maximum device	2.12.2009	EN 12470-3:2000 Note 2.1	21.3.2010
CEN	EN 12470-4:2000+A1:2009 Clinical thermometers — Part 4: Performance of electrical thermometers for continuous measurement	2.12.2009	EN 12470-4:2000 Note 2.1	21.3.2010
CEN	EN 12470-5:2003 Clinical thermometers — Part 5: Performance of infra-red ear thermometers (with maximum device)	7.11.2003		

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CEN	EN ISO 12870:2009 Ophthalmic optics — Spectacle frames — Requirements and test methods (ISO 12870:2004)	2.12.2009	EN ISO 12870:2004 Note 2.1	21.3.2010
CEN	EN 13060:2014 Small steam sterilizers	10.7.2015	EN 13060:2004 +A2:2010 Note 2.1	The date of this publication
CEN	EN ISO 13408-1:2015 Aseptic processing of health care products — Part 1: General requirements (ISO 13408-1:2008, including Amd 1:2013)	13.5.2016	EN ISO 13408-1:2011 Note 2.1	30.6.2016
CEN	EN ISO 13408-2:2011 Aseptic processing of health care products — Part 2: Filtration (ISO 13408-2:2003)	19.8.2011	EN 13824:2004 Note 2.1	31.12.2011
CEN	EN ISO 13408-3:2011 Aseptic processing of health care products — Part 3: Lyophilization (ISO 13408-3:2006)	19.8.2011	EN 13824:2004 Note 2.1	31.12.2011
CEN	EN ISO 13408-4:2011 Aseptic processing of health care products — Part 4: Clean-in-place technologies (ISO 13408-4:2005)	19.8.2011	EN 13824:2004 Note 2.1	31.12.2011

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CEN	EN ISO 13408-5:2011 Aseptic processing of health care products — Part 5: Sterilization in place (ISO 13408-5:2006)	19.8.2011	EN 13824:2004 Note 2.1	31.12.2011
CEN	EN ISO 13408-6:2011 Aseptic processing of health care products — Part 6: Isolator systems (ISO 13408-6:2005)	19.8.2011	EN 13824:2004 Note 2.1	31.12.2011
CEN	EN ISO 13408-7:2015 Aseptic processing of health care products — Part 7: Alternative processes for medical devices and combination products (ISO 13408-7:2012)	13.5.2016		
CEN	EN ISO 13485:2016 Medical devices — Quality management systems — Requirements for regulatory purposes (ISO 13485:2016)	This is the first publication	EN ISO 13485:2012 Note 2.1	31.3.2019
	EN ISO 13485:2016/AC:2016	This is the first publication		
CEN	EN 13544-1:2007+A1:2009 Respiratory therapy equipment — Part 1: Nebulizing systems and their components	7.7.2010	EN 13544-1:2007 Note 2.1	21.3.2010
CEN	EN 13544-2:2002+A1:2009 Respiratory therapy equipment — Part 2: Tubing and connectors	7.7.2010	EN 13544-2:2002 Note 2.1	21.3.2010
CEN	EN 13544-3:2001+A1:2009 Respiratory therapy equipment — Part 3: Air entrainment devices	7.7.2010	EN 13544-3:2001 Note 2.1	21.3.2010
CEN	EN 13624:2003 Chemical disinfectants and antiseptics — Quantitative suspension test for the evaluation of fungicidal activity of chemical disinfectants for instruments used in the medical area — Test method and requirements (phase 2, step 1)	30.9.2005		
CEN	EN 13718-1:2008 Medical vehicles and their equipment — Air ambulances — Part 1: Requirements for medical devices used in air ambulances	19.2.2009	EN 13718-1:2002 Note 2.1	28.2.2009
CEN	EN 13718-2:2015 Medical vehicles and their equipment — Air ambulances — Part 2: Operational and technical requirements for air ambulances	10.7.2015		

(1)	(2)	(3)	(4)	(5)
CEN	EN 13726-1:2002 Test methods for primary wound dressings — Part 1: Aspects of absorbency	27.3.2003		
	EN 13726-1:2002/AC:2003	2.12.2009		
CEN	EN 13726-2:2002 Test methods for primary wound dressings — Part 2: Moisture vapour transmission rate of permeable film dressings	27.3.2003		
CEN	EN 13727:2012 Chemical disinfectants and antiseptics — Quantitative suspension test for the evaluation of bactericidal activity in the medical area — Test method and requirements (phase 2, step 1)	30.8.2012	EN 13727:2003 Note 2.1	30.11.2012
CEN	EN 13867:2002+A1:2009 Concentrates for haemodialysis and related therapies	2.12.2009	EN 13867:2002 Note 2.1	21.3.2010
CEN	EN 13976-1:2011 Rescue systems — Transportation of incubators — Part 1: Interface conditions	19.8.2011	EN 13976-1:2003 Note 2.1	30.11.2011
CEN	EN 13976-2:2011 Rescue systems — Transportation of incubators — Part 2: System requirements	19.8.2011	EN 13976-2:2003 Note 2.1	30.11.2011
CEN	EN 14079:2003 Non-active medical devices — Performance requirements and test methods for absorbent cotton gauze and absorbent cotton and viscose gauze	30.9.2005		
CEN	EN 14139:2010 Ophthalmic optics — Specifications for ready-to-wear spectacles	18.1.2011		
CEN	EN ISO 14155:2011 Clinical investigation of medical devices for human subjects — Good clinical practice (ISO 14155:2011)	27.4.2012	EN ISO 14155:2011 Note 2.1	30.4.2012
	EN ISO 14155:2011/AC:2011	This is the first publication		
CEN	EN 14180:2003+A2:2009 Sterilizers for medical purposes — Low temperature steam and formaldehyde sterilizers — Requirements and testing	7.7.2010	EN 14180:2003 +A1:2009 Note 2.1	21.3.2010

(1)	(2)	(3)	(4)	(5)
CEN	EN 14348:2005 Chemical disinfectants and antiseptics — Quantitative suspension test for the evaluation of mycobactericidal activity of chemical disinfectants in the medical area including instrument disinfectants — Test methods and requirements (phase 2, step 1)	30.9.2005		
CEN	EN ISO 14408:2009 Tracheal tubes designed for laser surgery — Requirements for marking and accompanying information (ISO 14408:2005)	2.12.2009	EN ISO 14408:2005 Note 2.1	21.3.2010
CEN	EN 14561:2006 Chemical disinfectants and antiseptics — Quantitative carrier test for the evaluation of bactericidal activity for instruments used in the medical area — Test method and requirements (phase 2, step 2)	15.11.2006		
CEN	EN 14562:2006 Chemical disinfectants and antiseptics — Quantitative carrier test for the evaluation of fungicidal or yeasticidal activity for instruments used in the medical area — Test method and requirements (phase 2, step 2)	15.11.2006		
CEN	EN 14563:2008 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 — Test method and requirements (phase 2, step 2)	19.2.2009		
CEN	EN ISO 14602:2011 Non-active surgical implants — Implants for osteosynthesis — Particular requirements (ISO 14602:2010)	27.4.2012	EN ISO 14602:2010 Note 2.1	30.4.2012
CEN	EN ISO 14607:2009 Non-active surgical implants — Mammary implants — Particular requirements (ISO 14607:2007)	2.12.2009	EN ISO 14607:2007 Note 2.1	21.3.2010
CEN	EN ISO 14630:2009 Non-active surgical implants — General requirements (ISO 14630:2008)	2.12.2009	EN ISO 14630:2008 Note 2.1	21.3.2010
CEN	EN 14683:2005 Surgical masks — Requirements and test methods	2.6.2006		

(1)	(2)	(3)	(4)	(5)
CEN	EN ISO 14889:2009 Ophthalmic optics — Spectacle lenses — Fundamental requirements for uncut finished lenses (ISO 14889:2003)	2.12.2009	EN ISO 14889:2003 Note 2.1	21.3.2010
CEN	EN 14931:2006 Pressure vessels for human occupancy (PVHO) — Multi-place pressure chamber systems for hyperbaric therapy — Performance, safety requirements and testing	15.11.2006		
CEN	EN ISO 14937:2009 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 (ISO 14937:2009)	7.7.2010	EN ISO 14937:2000 Note 2.1	30.4.2010
CEN	EN ISO 14971:2012 Medical devices — Application of risk management to medical devices (ISO 14971:2007, Corrected version 2007-10-01)	30.8.2012	EN ISO 14971:2009 Note 2.1	30.8.2012
CEN	EN ISO 15001:2011 Anaesthetic and respiratory equipment — Compatibility with oxygen (ISO 15001:2010)	27.4.2012	EN ISO 15001:2010 Note 2.1	30.4.2012
CEN	EN ISO 15002:2008 Flow-metering devices for connection to terminal units of medical gas pipeline systems (ISO 15002:2008)	19.2.2009	EN 13220:1998 Note 2.1	31.7.2010
CEN	EN ISO 15004-1:2009 Ophthalmic instruments — Fundamental requirements and test methods — Part 1: General requirements applicable to all ophthalmic instruments (ISO 15004-1:2006)	2.12.2009	EN ISO 15004-1:2006 Note 2.1	21.3.2010
CEN	EN ISO 15223-1:2016 Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied — Part 1: General requirements (ISO 15223-1:2016, Corrected version 2017-03)	This is the first publication	EN 980:2008 Note 2.1	31.12.2017
CEN	EN ISO 15747:2011 Plastic containers for intravenous injections (ISO 15747:2010)	27.4.2012	EN ISO 15747:2010 Note 2.1	30.4.2012
CEN	EN ISO 15798:2010 Ophthalmic implants — Ophthalmic viscosurgical devices (ISO 15798:2010)	7.7.2010		

(1)	(2)	(3)	(4)	(5)
CEN	EN ISO 15883-1:2009 Washer-disinfectors — Part 1: General requirements, terms and definitions and tests (ISO 15883-1:2006)	2.12.2009	EN ISO 15883-1:2006 Note 2.1	21.3.2010
CEN	EN ISO 15883-2:2009 Washer-disinfectors — Part 2: Requirements and tests for washer-disinfectors employing thermal disinfection for surgical instruments, anaesthetic equipment, bowls, dishes, receivers, utensils, glassware, etc. (ISO 15883-2:2006)	2.12.2009	EN ISO 15883-2:2006 Note 2.1	21.3.2010
CEN	EN ISO 15883-3:2009 Washer-disinfectors — Part 3: Requirements and tests for washer-disinfectors employing thermal disinfection for human waste containers (ISO 15883-3:2006)	2.12.2009	EN ISO 15883-3:2006 Note 2.1	21.3.2010
CEN	EN ISO 15883-4:2009 Washer-disinfectors — Part 4: Requirements and tests for washer-disinfectors employing chemical disinfection for thermolabile endoscopes (ISO 15883-4:2008)	2.12.2009	EN ISO 15883-4:2008 Note 2.1	21.3.2010
CEN	EN 15986:2011 Symbol for use in the labelling of medical devices — Requirements for labelling of medical devices containing phthalates	13.5.2011		
CEN	EN ISO 16061:2009 Instrumentation for use in association with non-active surgical implants — General requirements (ISO 16061:2008, Corrected version 2009-03-15)	7.7.2010	EN ISO 16061:2008 Note 2.1	28.2.2010
CEN	EN ISO 16201:2006 Technical aids for disabled persons — Environmental control systems for daily living (ISO 16201:2006)	19.2.2009		
CEN	EN ISO 17510-1:2009 Sleep apnoea breathing therapy — Part 1: Sleep apnoea breathing therapy equipment (ISO 17510-1:2007)	2.12.2009	EN ISO 17510-1:2007 Note 2.1	21.3.2010
CEN	EN ISO 17510-2:2009 Sleep apnoea breathing therapy — Part 2: Masks and application accessories (ISO 17510-2:2007)	2.12.2009	EN ISO 17510-2:2007 Note 2.1	21.3.2010
CEN	EN ISO 17664:2004 Sterilization of medical devices — Information to be provided by the manufacturer for the processing of resterilizable medical devices (ISO 17664:2004)	30.9.2005		

(1)	(2)	(3)	(4)	(5)
CEN	EN ISO 17665-1:2006 Sterilization of health care products — Moist heat — Part 1: Requirements for the development, validation and routine control of a sterilization process for medical devices (ISO 17665-1:2006)	15.11.2006	EN 554:1994 Note 2.1	31.8.2009
CEN	EN ISO 18777:2009 Transportable liquid oxygen systems for medical use — Particular requirements (ISO 18777:2005)	2.12.2009	EN ISO 18777:2005 Note 2.1	21.3.2010
CEN	EN ISO 18778:2009 Respiratory equipment — Infant monitors — Particular requirements (ISO 18778:2005)	2.12.2009	EN ISO 18778:2005 Note 2.1	21.3.2010
CEN	EN ISO 18779:2005 Medical devices for conserving oxygen and oxygen mixtures — Particular requirements (ISO 18779:2005)	30.9.2005		
CEN	EN ISO 19054:2006 Rail systems for supporting medical equipment (ISO 19054:2005)	7.9.2006	EN 12218:1998 Note 2.1	30.6.2008
CEN	EN 20594-1:1993 Conical fittings with a 6 % (Luer) taper for syringes, needles and certain other medical equipment — Part 1: General requirements (ISO 594-1:1986)	18.11.1995		
	EN 20594-1:1993/A1:1997	10.8.1999	Note 3	31.5.1998
	EN 20594-1:1993/AC:1996	2.12.2009		
CEN	EN ISO 21534:2009 Non-active surgical implants — Joint replacement implants — Particular requirements (ISO 21534:2007)	2.12.2009	EN ISO 21534:2007 Note 2.1	21.3.2010
CEN	EN ISO 21535:2009 Non-active surgical implants — Joint replacement implants — Specific requirements for hip-joint replacement implants (ISO 21535:2007)	2.12.2009	EN ISO 21535:2007 Note 2.1	21.3.2010
CEN	EN ISO 21536:2009 Non-active surgical implants — Joint replacement implants — Specific requirements for knee-joint replacement implants (ISO 21536:2007)	2.12.2009	EN ISO 21536:2007 Note 2.1	21.3.2010
CEN	EN ISO 21649:2009 Needle-free injectors for medical use — Requirements and test methods (ISO 21649:2006)	7.7.2010	EN ISO 21649:2006 Note 2.1	21.3.2010

(1)	(2)	(3)	(4)	(5)
CEN	EN ISO 21969:2009 High-pressure flexible connections for use with medical gas systems (ISO 21969:2009)	7.7.2010	EN ISO 21969:2006 Note 2.1	31.5.2010
CEN	EN ISO 21987:2009 Ophthalmic optics — Mounted spectacle lenses (ISO 21987:2009)	7.7.2010		
CEN	EN ISO 22442-1:2007 Medical devices utilizing animal tissues and their derivatives — Part 1: Application of risk management (ISO 22442-1:2007)	27.2.2008	EN 12442-1:2000 Note 2.1	30.6.2008
CEN	EN ISO 22442-2:2007 Medical devices utilizing animal tissues and their derivatives — Part 2: Controls on sourcing, collection and handling (ISO 22442-2:2007)	27.2.2008	EN 12442-2:2000 Note 2.1	30.6.2008
CEN	EN ISO 22442-3:2007 Medical devices utilizing animal tissues and their derivatives — Part 3: Validation of the elimination and/or inactivation of viruses and transmissible spongiform encephalopathy (TSE) agents (ISO 22442-3:2007)	27.2.2008	EN 12442-3:2000 Note 2.1	30.6.2008
CEN	EN ISO 22523:2006 External limb prostheses and external orthoses — Requirements and test methods (ISO 22523:2006)	9.8.2007	EN 12523:1999 Note 2.1	30.4.2007

This standard still needs to be amended to take into account the requirements introduced by Directive 2007/47/EC. The amended standard will be published by CEN as soon as possible. Manufacturers are advised to check whether all relevant Essential Requirements of the amended directive are appropriately covered.

CEN	EN ISO 22675:2016 Prosthetics — Testing of ankle-foot devices and foot units — Requirements and test methods (ISO 22675:2016)	This is the first publication	EN ISO 22675:2006 Note 2.1	30.6.2018
CEN	EN ISO 23328-1:2008 Breathing system filters for anaesthetic and respiratory use — Part 1: Salt test method to assess filtration performance (ISO 23328-1:2003)	19.2.2009	EN 13328-1:2001 Note 2.1	30.9.2008
CEN	EN ISO 23328-2:2009 Breathing system filters for anaesthetic and respiratory use — Part 2: Non-filtration aspects (ISO 23328-2:2002)	2.12.2009	EN ISO 23328-2:2008 Note 2.1	21.3.2010
CEN	EN ISO 23747:2009 Anaesthetic and respiratory equipment — Peak expiratory flow meters for the assessment of pulmonary function in spontaneously breathing humans (ISO 23747:2007)	2.12.2009	EN ISO 23747:2007 Note 2.1	21.3.2010

(1)	(2)	(3)	(4)	(5)
CEN	EN ISO 25539-1:2009 Cardiovascular implants — Endovascular devices — Part 1: Endovascular prostheses (ISO 25539-1:2003 including Amd 1:2005)	2.12.2009	EN 12006-3:1998 +A1:2009 EN ISO 25539-1:2008 Note 2.1	21.3.2010
	EN ISO 25539-1:2009/AC:2011	30.8.2012		
CEN	EN ISO 25539-2:2009 Cardiovascular implants — Endovascular devices — Part 2: Vascular stents (ISO 25539-2:2008)	2.12.2009	EN 12006-3:1998 +A1:2009 EN ISO 25539-2:2008 Note 2.1	21.3.2010
	EN ISO 25539-2:2009/AC:2011	30.8.2012		
CEN	EN ISO 26782:2009 Anaesthetic and respiratory equipment — Spirometers intended for the measurement of time forced expired volumes in humans (ISO 26782:2009)	7.7.2010		
	EN ISO 26782:2009/AC:2009	7.7.2010		
CEN	EN 27740:1992 Instruments for surgery, scalpels with detachable blades, fitting dimensions (ISO 7740:1985)	18.11.1995		
	EN 27740:1992/A1:1997	10.8.1999	Note 3	31.5.1998
	EN 27740:1992/AC:1996	2.12.2009		
CEN	EN ISO 81060-1:2012 Non-invasive sphygmomanometers — Part 1: Requirements and test methods for non-automated measurement type (ISO 81060-1:2007)	30.8.2012	EN 1060-1:1995 +A2:2009 EN 1060-2:1995 +A1:2009 Note 2.1	31.5.2015
Cenelec	EN 60118-13:2005 Electroacoustics — Hearing aids — Part 13: Electromagnetic compatibility (EMC) IEC 60118-13:2004	19.1.2006	EN 60118-13:1997 Note 2.1	1.2.2008

(*): This European Standard does not necessarily cover the requirements introduced by Directive 2007/47/EC.

Cenelec	EN 60522:1999 Determination of the permanent filtration of X-ray tube assemblies IEC 60522:1999	14.11.2001		

(*): This European Standard does not necessarily cover the requirements introduced by Directive 2007/47/EC.

Cenelec	EN 60580:2000 Medical electrical equipment — Dose area product meters IEC 60580:2000	13.12.2002		

(1)	(2)	(3)	(4)	(5)

(*): This European Standard does not necessarily cover the requirements introduced by Directive 2007/47/EC.

Cenelec	EN 60601-1:2006 Medical electrical equipment — Part 1: General requirements for basic safety and essential performance IEC 60601-1:2005	27.11.2008	EN 60601-1:1990 + A13:1996 + A1:1993 + A2:1995 EN 60601-1-1:2001 EN 60601-1-4:1996 + A1:1999 Note 2.1	1.6.2012
	EN 60601-1:2006/AC:2010	18.1.2011		
	EN 60601-1:2006/A1:2013 IEC 60601-1:2005/A1:2012	16.5.2014	Note 3	31.12.2017

Addendum to Note 1 and Note 3 concerning dates of cessation of presumption of conformity when applying EN 60601-1:2006.
The date of cessation of presumption of conformity when applying EN 60601-1:2006 is 31.12.2017. However the Annex ZZ to EN 60601-1:2006 ceases to specify the presumption of conformity with the Essential Requirements of Directive 93/42/EEC on 31.12.2015. As from 1.1.2016, only the clauses and sub-clauses of EN 60601-1:2006 corresponding to the clauses and sub-clauses referred to in Annex ZZ to EN 60601-1:2006/A1:2013 provide presumption of conformity with the Essential Requirements of Directive 93/42/EEC, to the extent indicated in the Annex ZZ to EN 60601-1:2006/A1:2013.

Cenelec	EN 60601-1-1:2001 Medical electrical equipment — Part 1-1: General requirements for safety — Collateral standard: Safety requirements for medical electrical systems IEC 60601-1-1:2000	14.11.2001	EN 60601-1-1:1993 + A1:1996 Note 2.1	1.11.2003

(*): This European Standard does not necessarily cover the requirements introduced by Directive 2007/47/EC.

Cenelec	EN 60601-1-2:2015 Medical electrical equipment — Part 1-2: General requirements for basic safety and essential performance — Collateral Standard: Electromagnetic disturbances — Requirements and tests IEC 60601-1-2:2014	13.5.2016	EN 60601-1-2:2007 Note 2.1	31.12.2018
Cenelec	EN 60601-1-3:2008 Medical electrical equipment — Part 1-3: General requirements for basic safety and essential performance — Collateral Standard: Radiation protection in diagnostic X-ray equipment IEC 60601-1-3:2008	27.11.2008	EN 60601-1-3:1994 Note 2.1	1.6.2012
	EN 60601-1-3:2008/AC:2010	18.1.2011		
	EN 60601-1-3:2008/A11:2016	This is the first publication	Note 3	1.11.2019

(*): This European Standard does not necessarily cover the requirements introduced by Directive 2007/47/EC.

(1)	(2)	(3)	(4)	(5)
Cenelec	EN 60601-1-4:1996 Medical electrical equipment — Part 1-4: General requirements for safety — Collateral standard: Programmable electrical medical systems IEC 60601-1-4:1996	8.11.1997		
	EN 60601-1-4:1996/A1:1999 IEC 60601-1-4:1996/A1:1999	8.11.1997	Note 3	1.12.2002

(*): This European Standard does not necessarily cover the requirements introduced by Directive 2007/47/EC.

Cenelec	EN 60601-1-6:2010 Medical electrical equipment — Part 1-6: General requirements for basic safety and essential performance — Collateral standard: Usability IEC 60601-1-6:2010	18.1.2011	EN 60601-1-6:2007 Note 2.1	1.4.2013

(*): This European Standard does not necessarily cover the requirements introduced by Directive 2007/47/EC.

Cenelec	EN 60601-1-8:2007 Medical electrical equipment — Part 1-8: General requirements for basic safety and essential performance — Collateral Standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems IEC 60601-1-8:2006	27.11.2008	EN 60601-1-8:2004 + A1:2006 Note 2.1	1.6.2012
	EN 60601-1-8:2007/AC:2010	18.1.2011		
	EN 60601-1-8:2007/A11:2017	This is the first publication	Note 3	7.1.2020

(*): This European Standard does not necessarily cover the requirements introduced by Directive 2007/47/EC.

Cenelec	EN 60601-1-10:2008 Medical electrical equipment — Part 1-10: General requirements for basic safety and essential performance — Collateral Standard: Requirements for the development of physiologic closed-loop controllers IEC 60601-1-10:2007	27.11.2008		

(*): This European Standard does not necessarily cover the requirements introduced by Directive 2007/47/EC.

Cenelec	EN 60601-1-11:2010 Medical electrical equipment — Part 1-11: General requirements for basic safety and essential performance — Collateral standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment IEC 60601-1-11:2010	18.1.2011		

(*): This European Standard does not necessarily cover the requirements introduced by Directive 2007/47/EC.

(1)	(2)	(3)	(4)	(5)
Cenelec	EN 60601-2-1:1998 Medical electrical equipment — Part 2-1: Particular requirements for the safety of electron accelerators in the range of 1 MeV to 50 MeV IEC 60601-2-1:1998	14.11.2001		
	EN 60601-2-1:1998/A1:2002 IEC 60601-2-1:1998/A1:2002	13.12.2002	Note 3	1.6.2005
(*): This European Standard does not necessarily cover the requirements introduced by Directive 2007/47/EC.				
Cenelec	EN 60601-2-2:2009 Medical electrical equipment — Part 2-2: Particular requirements for the basic safety and essential performance of high frequency surgical equipment and high frequency surgical accessories IEC 60601-2-2:2009	7.7.2010	EN 60601-2-2:2007 Note 2.1	1.4.2012
(*): This European Standard does not necessarily cover the requirements introduced by Directive 2007/47/EC.				
Cenelec	EN 60601-2-3:1993 Medical electrical equipment — Part 2: Particular requirements for the safety of short-wave therapy equipment IEC 60601-2-3:1991	18.11.1995		
	EN 60601-2-3:1993/A1:1998 IEC 60601-2-3:1991/A1:1998	18.11.1995	Note 3	1.7.2001
(*): This European Standard does not necessarily cover the requirements introduced by Directive 2007/47/EC.				
Cenelec	EN 60601-2-4:2003 Medical electrical equipment — Part 2-4: Particular requirements for the safety of cardiac defibrillators IEC 60601-2-4:2002	15.10.2003		
(*): This European Standard does not necessarily cover the requirements introduced by Directive 2007/47/EC.				
Cenelec	EN 60601-2-5:2000 Medical electrical equipment — Part 2-5: Particular requirements for the safety of ultrasonic physiotherapy equipment IEC 60601-2-5:2000	13.12.2002		
(*): This European Standard does not necessarily cover the requirements introduced by Directive 2007/47/EC.				
Cenelec	EN 60601-2-8:1997 Medical electrical equipment — Part 2: Particular requirements for the safety of therapeutic X-ray equipment operating in the range 10 kV to 1 MV IEC 60601-2-8:1987	14.11.2001		
	EN 60601-2-8:1997/A1:1997 IEC 60601-2-8:1987/A1:1997	14.11.2001	Note 3	1.7.1998
(*): This European Standard does not necessarily cover the requirements introduced by Directive 2007/47/EC.				

(1)	(2)	(3)	(4)	(5)
Cenelec	EN 60601-2-10:2000 Medical electrical equipment — Part 2-10: Particular requirements for the safety of nerve and muscle stimulators IEC 60601-2-10:1987	13.12.2002		
	EN 60601-2-10:2000/A1:2001 IEC 60601-2-10:1987/A1:2001	13.12.2002	Note 3	1.11.2004

(*): This European Standard does not necessarily cover the requirements introduced by Directive 2007/47/EC.

Cenelec	EN 60601-2-11:1997 Medical electrical equipment — Part 2-11: Particular requirements for the safety of gamma beam therapy equipment IEC 60601-2-11:1997	9.10.1999		
	EN 60601-2-11:1997/A1:2004 IEC 60601-2-11:1997/A1:2004	9.10.1999	Note 3	1.9.2007

(*): This European Standard does not necessarily cover the requirements introduced by Directive 2007/47/EC.

Cenelec	EN 60601-2-12:2006 Medical electrical equipment — Part 2-12: Particular requirements for the safety of lung ventilators — Critical care ventilators IEC 60601-2-12:2001	22.12.2007		

(*): This European Standard does not necessarily cover the requirements introduced by Directive 2007/47/EC.

Cenelec	EN 60601-2-13:2006 Medical electrical equipment — Part 2-13: Particular requirements for the safety and essential performance of anaesthetic systems IEC 60601-2-13:2003	22.12.2007		
	EN 60601-2-13:2006/A1:2007 IEC 60601-2-13:2003/A1:2006	22.12.2007	Note 3	1.3.2010

(*): This European Standard does not necessarily cover the requirements introduced by Directive 2007/47/EC.

Cenelec	EN 60601-2-16:1998 Medical electrical equipment — Part 2-16: Particular requirements for the safety of haemodialysis, haemodiafiltration and haemofiltration equipment IEC 60601-2-16:1998	9.10.1999		
	EN 60601-2-16:1998/AC:1999	18.1.2011		

(*): This European Standard does not necessarily cover the requirements introduced by Directive 2007/47/EC.

Cenelec	EN 60601-2-17:2004 Medical electrical equipment — Part 2-17: Particular requirements for the safety of automatically-controlled brachytherapy afterloading equipment IEC 60601-2-17:2004	8.11.2005	EN 60601-2-17:1996 + A1:1996 Note 2.1	1.3.2007

(*): This European Standard does not necessarily cover the requirements introduced by Directive 2007/47/EC.

(1)	(2)	(3)	(4)	(5)
Cenelec	EN 60601-2-18:1996 Medical electrical equipment — Part 2: Particular requirements for the safety of endoscopic equipment IEC 60601-2-18:1996	9.10.1999		
	EN 60601-2-18:1996/A1:2000 IEC 60601-2-18:1996/A1:2000	9.10.1999	Note 3	1.8.2003
(*): This European Standard does not necessarily cover the requirements introduced by Directive 2007/47/EC.				
Cenelec	EN 60601-2-19:2009 Medical electrical equipment — Part 2-19: Particular requirements for the basic safety and essential performance of infant incubators IEC 60601 IEC 60601-2-19:2009	7.7.2010	EN 60601-2-19:1996 + A1:1996 Note 2.1	1.4.2012
(*): This European Standard does not necessarily cover the requirements introduced by Directive 2007/47/EC.				
Cenelec	EN 60601-2-20:2009 Medical electrical equipment — Part 2-20: Particular requirements for the basic safety and essential performance of infant transport incubators IEC 60601 IEC 60601-2-20:2009	18.1.2011	EN 60601-2-20:1996 Note 2.1	1.9.2012
(*): This European Standard does not necessarily cover the requirements introduced by Directive 2007/47/EC.				
Cenelec	EN 60601-2-21:2009 Medical electrical equipment — Part 2-21: Particular requirements for the basic safety and essential performance of infant radiant warmers IEC 60601-2-21:2009	7.7.2010	EN 60601-2-21:1994 + A1:1996 Note 2.1	1.4.2012
(*): This European Standard does not necessarily cover the requirements introduced by Directive 2007/47/EC.				
Cenelec	EN 60601-2-22:1996 Medical electrical equipment — Part 2: Particular requirements for the safety of diagnostic and therapeutic laser equipment IEC 60601-2-22:1995	17.5.1997		
(*): This European Standard does not necessarily cover the requirements introduced by Directive 2007/47/EC.				
Cenelec	EN 60601-2-23:2000 Medical electrical equipment — Part 2-23: Particular requirements for the safety, including essential performance, of transcutaneous partial pressure monitoring equipment IEC 60601-2-23:1999	14.11.2001	EN 60601-2-23:1997 Note 2.1	1.1.2003
(*): This European Standard does not necessarily cover the requirements introduced by Directive 2007/47/EC.				
Cenelec	EN 60601-2-24:1998 Medical electrical equipment — Part 2-24: Particular requirements for the safety of infusion pumps and controllers IEC 60601-2-24:1998	9.10.1999		
(*): This European Standard does not necessarily cover the requirements introduced by Directive 2007/47/EC.				

(1)	(2)	(3)	(4)	(5)
Cenelec	EN 60601-2-25:1995 Medical electrical equipment — Part 2-25: Particular requirements for the safety of electrocardiographs IEC 60601-2-25:1993	17.5.1997		
	EN 60601-2-25:1995/A1:1999 IEC 60601-2-25:1993/A1:1999	13.12.2002	Note 3	1.5.2002

(*): This European Standard does not necessarily cover the requirements introduced by Directive 2007/47/EC.

Cenelec	EN 60601-2-26:2003 Medical electrical equipment — Part 2-26: Particular requirements for the safety of electroencephalographs IEC 60601-2-26:2002	8.11.2005	EN 60601-2-26:1994 Note 2.1	1.3.2006

(*): This European Standard does not necessarily cover the requirements introduced by Directive 2007/47/EC.

Cenelec	EN 60601-2-27:2006 Medical electrical equipment — Part 2-27: Particular requirements for the safety, including essential performance, of electrocardiographic monitoring equipment IEC 60601-2-27:2005	26.7.2006	EN 60601-2-27:1994 Note 2.1	1.11.2008
	EN 60601-2-27:2006/AC:2006	18.1.2011		

(*): This European Standard does not necessarily cover the requirements introduced by Directive 2007/47/EC.

Cenelec	EN 60601-2-28:2010 Medical electrical equipment — Part 2-28: Particular requirements for the basic safety and essential performance of X-ray tube assemblies for medical diagnosis IEC 60601-2-28:2010	18.1.2011	EN 60601-2-28:1993 Note 2.1	1.4.2013

(*): This European Standard does not necessarily cover the requirements introduced by Directive 2007/47/EC.

Cenelec	EN 60601-2-29:2008 Medical electrical equipment — Part 2-29: Particular requirements for the basic safety and essential performance of radiotherapy simulators IEC 60601-2-29:2008	15.7.2009	EN 60601-2-29:1999 Note 2.1	1.11.2011

(*): This European Standard does not necessarily cover the requirements introduced by Directive 2007/47/EC.

Cenelec	EN 60601-2-30:2000 Medical electrical equipment — Part 2-30: Particular requirements for the safety, including essential performance, of automatic cycling non-invasive blood pressure monitoring equipment IEC 60601-2-30:1999	14.11.2001	EN 60601-2-30:1995 Note 2.1	1.2.2003

(*): This European Standard does not necessarily cover the requirements introduced by Directive 2007/47/EC.

(1)	(2)	(3)	(4)	(5)
Cenelec	EN 60601-2-33:2010 Medical electrical equipment — Part 2-33: Particular requirements for the basic safety and essential performance of magnetic resonance equipment for medical diagnosis IEC 60601 IEC 60601-2-33:2010	This is the first publication	EN 60601-2-33:2002 + A1:2005 + A2:2008 Note 2.1	31.12.2017
	EN 60601-2-33:2010/A1:2015 IEC 60601-2-33:2010/A1:2013	This is the first publication	Note 3	14.4.2018
	EN 60601-2-33:2010/A2:2015 IEC 60601-2-33:2010/A2:2015	This is the first publication	Note 3	23.7.2018
	EN 60601-2-33:2010/AC:2016-03	This is the first publication		
	EN 60601-2-33:2010/A12:2016	This is the first publication	Note 3	1.11.2019
Cenelec	EN 60601-2-34:2000 Medical electrical equipment — Part 2-34: Particular requirements for the safety, including essential performance, of invasive blood pressure monitoring equipment IEC 60601-2-34:2000	15.10.2003	EN 60601-2-34:1995 Note 2.1	1.11.2003

(*): This European Standard does not necessarily cover the requirements introduced by Directive 2007/47/EC.

Cenelec	EN 60601-2-36:1997 Medical electrical equipment — Part 2: Particular requirements for the safety of equipment for extracorporeally induced lithotripsy IEC 60601-2-36:1997	9.10.1999		

(*): This European Standard does not necessarily cover the requirements introduced by Directive 2007/47/EC.

Cenelec	EN 60601-2-37:2008 Medical electrical equipment — Part 2-37: Particular requirements for the basic safety and essential performance of ultrasonic medical diagnostic and monitoring equipment IEC 60601-2-37:2007	27.11.2008	EN 60601-2-37:2001 + A1:2005 + A2:2005 Note 2.1	1.10.2010

(*): This European Standard does not necessarily cover the requirements introduced by Directive 2007/47/EC.

Cenelec	EN 60601-2-39:2008 Medical electrical equipment — Part 2-39: Particular requirements for basic safety and essential performance of peritoneal dialysis equipment IEC 60601-2-39:2007	27.11.2008	EN 60601-2-39:1999 Note 2.1	1.3.2011

(*): This European Standard does not necessarily cover the requirements introduced by Directive 2007/47/EC.

(1)	(2)	(3)	(4)	(5)
Cenelec	EN 60601-2-40:1998 Medical electrical equipment — Part 2-40: Particular requirements for the safety of electromyographs and evoked response equipment IEC 60601-2-40:1998	9.10.1999		
(*): This European Standard does not necessarily cover the requirements introduced by Directive 2007/47/EC.				
Cenelec	EN 60601-2-41:2009 Medical electrical equipment — Part 2-41: Particular requirements for basic safety and essential performance of surgical luminaires and luminaires for diagnosis IEC 60601-2-41:2009	18.1.2011	EN 60601-2-41:2000 Note 2.1	1.11.2012
(*): This European Standard does not necessarily cover the requirements introduced by Directive 2007/47/EC.				
Cenelec	EN 60601-2-43:2010 Medical electrical equipment — Part 2-43: Particular requirements for basic safety and essential performance of X-ray equipment for interventional procedures IEC 60601-2-43:2010	18.1.2011	EN 60601-2-43:2000 Note 2.1	1.6.2013
(*): This European Standard does not necessarily cover the requirements introduced by Directive 2007/47/EC.				
Cenelec	EN 60601-2-44:2009 Medical electrical equipment — Part 2-44: Particular requirements for the basic safety and essential performance of X-ray equipment for computed tomography IEC 60601-2-44:2009	7.7.2010	EN 60601-2-44:2001 + A1:2003 Note 2.1	1.5.2012
(*): This European Standard does not necessarily cover the requirements introduced by Directive 2007/47/EC.				
Cenelec	EN 60601-2-45:2001 Medical electrical equipment — Part 2-45: Particular requirements for the safety of mammographic X-ray equipment and mammographic stereotactic devices IEC 60601-2-45:2001	14.11.2001	EN 60601-2-45:1998 Note 2.1	1.7.2004
(*): This European Standard does not necessarily cover the requirements introduced by Directive 2007/47/EC.				
Cenelec	EN 60601-2-46:1998 Medical electrical equipment — Part 2-46: Particular requirements for the safety of operating tables IEC 60601-2-46:1998	14.11.2001		
(*): This European Standard does not necessarily cover the requirements introduced by Directive 2007/47/EC.				
Cenelec	EN 60601-2-47:2001 Medical electrical equipment — Part 2-47: Particular requirements for the safety, including essential performance, of ambulatory electrocardiographic systems IEC 60601-2-47:2001	13.12.2002		
(*): This European Standard does not necessarily cover the requirements introduced by Directive 2007/47/EC.				

(1)	(2)	(3)	(4)	(5)
Cenelec	EN 60601-2-49:2001 Medical electrical equipment — Part 2-49: Particular requirements for the safety of multi-function patient monitoring equipment IEC 60601-2-49:2001	13.12.2002		
(*): This European Standard does not necessarily cover the requirements introduced by Directive 2007/47/EC.				
Cenelec	EN 60601-2-50:2009 Medical electrical equipment — Part 2-50: Particular requirements for the basic safety and essential performance of infant phototherapy equipment IEC 60601-2-50:2009	7.7.2010	EN 60601-2-50:2002 Note 2.1	1.5.2012
(*): This European Standard does not necessarily cover the requirements introduced by Directive 2007/47/EC.				
Cenelec	EN 60601-2-51:2003 Medical electrical equipment — Part 2-51: Particular requirements for safety, including essential performance, of recording and analysing single channel and multichannel electrocardiographs IEC 60601-2-51:2003	24.6.2004		
(*): This European Standard does not necessarily cover the requirements introduced by Directive 2007/47/EC.				
Cenelec	EN 60601-2-52:2010 Medical electrical equipment — Part 2-52: Particular requirements for basic safety and essential performance of medical beds (IEC 60601-2-52:2009)	13.5.2011	EN 1970:2000 + A1:2005 EN 60601-2-38:1996 + A1:2000 Note 2.1	1.6.2012
	EN 60601-2-52:2010/AC:2011	30.8.2012		
(*): This European Standard does not necessarily cover the requirements introduced by Directive 2007/47/EC.				
Cenelec	EN 60601-2-54:2009 Medical electrical equipment — Part 2-54: Particular requirements for the basic safety and essential performance of X-ray equipment for radiography and radioscopy IEC 60601-2-54:2009	18.1.2011	EN 60601-2-7:1998 EN 60601-2-28:1993 EN 60601-2-32:1994 Note 2.1	1.8.2012
(*): This European Standard does not necessarily cover the requirements introduced by Directive 2007/47/EC.				
Cenelec	EN 60627:2001 Diagnostic X-ray imaging equipment — Characteristics of general purpose and mammographic anti-scatter grids IEC 60627:2001	13.12.2002		
	EN 60627:2001/AC:2002	18.1.2011		
(*): This European Standard does not necessarily cover the requirements introduced by Directive 2007/47/EC.				
Cenelec	EN 60645-1:2001 Electroacoustics — Audiological equipment — Part 1: Pure-tone audiometers IEC 60645-1:2001	13.12.2002	EN 60645-1:1994 Note 2.1	1.10.2004
(*): This European Standard does not necessarily cover the requirements introduced by Directive 2007/47/EC.				

(1)	(2)	(3)	(4)	(5)
Cenelec	EN 60645-2:1997 Audiometers — Part 2: Equipment for speech audiometry IEC 60645-2:1993	17.5.1997		

(*): This European Standard does not necessarily cover the requirements introduced by Directive 2007/47/EC.

Cenelec	EN 60645-3:2007 Electroacoustics — Audiometric equipment — Part 3: Test signals of short duration IEC 60645-3:2007	27.11.2008	EN 60645-3:1995 Note 2.1	1.6.2010

(*): This European Standard does not necessarily cover the requirements introduced by Directive 2007/47/EC.

Cenelec	EN 60645-4:1995 Audiometers — Part 4: Equipment for extended high-frequency audiometry IEC 60645-4:1994	23.8.1996		

(*): This European Standard does not necessarily cover the requirements introduced by Directive 2007/47/EC.

Cenelec	EN 61217:2012 Radiotherapy equipment — Coordinates, movements and scales IEC 61217:2011	30.8.2012	EN 61217:1996 + A1:2001 + A2:2008 Note 2.1	11.1.2015
Cenelec	EN 61676:2002 Medical electrical equipment — Dosimetric instruments used for non-invasive measurement of X-ray tube voltage in diagnostic radiology IEC 61676:2002	15.10.2003		
	EN 61676:2002/A1:2009 IEC 61676:2002/A1:2008	7.7.2010	Note 3	1.3.2012

(*): This European Standard does not necessarily cover the requirements introduced by Directive 2007/47/EC.

Cenelec	EN 62083:2009 Medical electrical equipment — Requirements for the safety of radiotherapy treatment planning systems IEC 62083:2009	18.1.2011	EN 62083:2001 Note 2.1	1.11.2012

(*): This European Standard does not necessarily cover the requirements introduced by Directive 2007/47/EC.

Cenelec	EN 62220-1:2004 Medical electrical equipment — Characteristics of digital X-ray imaging devices — Part 1: Determination of the detective quantum efficiency IEC 62220-1:2003	24.6.2004		

(*): This European Standard does not necessarily cover the requirements introduced by Directive 2007/47/EC.

(1)	(2)	(3)	(4)	(5)
Cenelec	EN 62220-1-2:2007 Medical electrical equipment — Characteristics of digital X-ray imaging devices — Part 1-2: Determination of the detective quantum efficiency — Detectors used in mammography IEC 62220-1-2:2007	27.11.2008		

(*): This European Standard does not necessarily cover the requirements introduced by Directive 2007/47/EC.

Cenelec	EN 62220-1-3:2008 Medical electrical equipment — Characteristics of digital X-ray imaging devices — Part 1-3: Determination of the detective quantum efficiency — Detectors used in dynamic imaging IEC 62220-1-3:2008	15.7.2009		

(*): This European Standard does not necessarily cover the requirements introduced by Directive 2007/47/EC.

Cenelec	EN 62304:2006 Medical device software — Software life-cycle processes IEC 62304:2006	27.11.2008		
	EN 62304:2006/AC:2008	18.1.2011		

(*): This European Standard does not necessarily cover the requirements introduced by Directive 2007/47/EC.

Cenelec	EN 62366:2008 Medical devices — Application of usability engineering to medical devices IEC 62366:2007	27.11.2008		

(*): This European Standard does not necessarily cover the requirements introduced by Directive 2007/47/EC.

Cenelec	EN 80601-2-35:2009 Medical electrical equipment — Part 2-35: Particular requirements for the basic safety and essential performance of heating devices using blankets, pads and mattresses and intended for heating in medical use IEC 80601-2-35:2009	18.1.2011	EN 60601-2-35:1996 Note 2.1	1.11.2012

(*): This European Standard does not necessarily cover the requirements introduced by Directive 2007/47/EC.

Cenelec	EN 80601-2-58:2009 Medical electrical equipment — Part 2-58: Particular requirements for the basic safety and essential performance of lens removal devices and vitrectomy devices for ophthalmic surgery IEC 80601-2-58:2008	7.7.2010		

(*): This European Standard does not necessarily cover the requirements introduced by Directive 2007/47/EC.

(1)	(2)	(3)	(4)	(5)
Cenelec	EN 80601-2-59:2009 Medical electrical equipment — Part 2-59: Particular requirements for the basic safety and essential performance of screening thermographs for human febrile temperature screening IEC 80601 IEC 80601-2-59:2008	18.1.2011		

(*): This European Standard does not necessarily cover the requirements introduced by Directive 2007/47/EC.

([1]) ESO: European standardisation organisation:
— CEN: Avenue Marnix 17, B-1000, Brussels, Tel. +32 2 5500811; fax + 32 2 5500819 (http://www.cen.eu)
— CENELEC: Avenue Marnix 17, B-1000, Brussels, Tel. +32 2 5196871; fax + 32 2 5196919 (http://www.cenelec.eu)
— ETSI: 650, route des Lucioles, F-06921 Sophia Antipolis, Tel. +33 492 944200; fax +33 493 654716, (http://www.etsi.eu)

Note 1: Generally the date of cessation of presumption of conformity will be the date of withdrawal ('dow'), set by the European standardisation organisation, but attention of users of these standards is drawn to the fact that in certain exceptional cases this can be otherwise.

Note 2.1: The new (or amended) standard has the same scope as the superseded standard. On the date stated, the superseded standard ceases to give presumption of conformity with the essential or other requirements of the relevant Union legislation.

Note 2.2: The new standard has a broader scope than the superseded standard. On the date stated, the superseded standard ceases to give presumption of conformity with the essential or other requirements of the relevant Union legislation.

Note 2.3: The new standard has a narrower scope than the superseded standard. On the date stated, the (partially) superseded standard ceases to give presumption of conformity with the essential or other requirements of the relevant Union legislation for those products or services that fall within the scope of the new standard. Presumption of conformity with the essential or other requirements of the relevant Union legislation for products or services that still fall within the scope of the (partially) superseded standard, but that do not fall within the scope of the new standard, is unaffected.

Note 3: In case of amendments, the referenced standard is EN CCCCC:YYYY, its previous amendments, if any, and the new, quoted amendment. The superseded standard therefore consists of EN CCCCC:YYYY and its previous amendments, if any, but without the new quoted amendment. On the date stated, the superseded standard ceases to give presumption of conformity with the essential or other requirements of the relevant Union legislation.

NOTE:

— Any information concerning the availability of the standards can be obtained either from the European standardisation organisations or from the national standardisation bodies the list of which is published in the *Official Journal of the European Union* according to Article 27 of the Regulation (EU) No 1025/2012 ([1]).

— Standards are adopted by the European standardisation organisations in English (CEN and Cenelec also publish in French and German). Subsequently, the titles of the standards are translated into all other required official languages of the European Union by the national standardisation bodies. The European Commission is not responsible for the correctness of the titles which have been presented for publication in the Official Journal.

— References to Corrigenda '…/AC:YYYY' are published for information only. A Corrigendum removes printing, linguistic or similar errors from the text of a standard and may relate to one or more language versions (English, French and/or German) of a standard as adopted by a European standardisation organisation.

([1]) OJ C 338, 27.9.2014, p. 31.

— Publication of the references in the *Official Journal of the European Union* does not imply that the standards are available in all the official languages of the European Union.

— This list replaces all the previous lists published in the *Official Journal of the European Union*. The European Commission ensures the updating of this list.

— More information about harmonised standards and other European standards on the Internet at

http://ec.europa.eu/growth/single-market/european-standards/harmonised-standards/index_en.htm