Commission communication in the framework of the implementation of the Council Directive 93/42/EEC of 14 June 1993 concerning medical devices

(Text with EEA relevance)

(Publication of titles and references of harmonised standards under the directive)

(2008/C 54/08)

ESO (1)	Reference and title of the harmonised standard (and reference document)	Reference of superseded standard	Date of cessation of presumption of conformity of superseded standard (Note 1)
CEN	EN 285:2006 Sterilization — Steam sterilizers — Large sterilizers	EN 285:1996	30.11.2008
CEN	EN 375:2001 Information supplied by the manufacturer with *in vitro* diagnostic reagents for professional use	—	
CEN	EN 376:2002 Information supplied by the manufacturer with *in vitro* diagnostic reagents for self-testing	—	
CEN	EN 455-1:2000 Medical gloves for single use — Part 1: Requirements and testing for freedom from holes	EN 455-1:1993	Date expired (30.4.2001)
CEN	EN 455-2:2000 Medical gloves for single use — Part 2: Requirements and testing for physical properties (including Technical Corrigendum 1:1996)	EN 455-2:1995	Date expired (30.4.2001)
CEN	EN 455-3:2006 Medical gloves for single use — Part 3: Requirements and testing for biological evaluation	EN 455-3:1999	Date expired (30.6.2007)
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 EN 556-1:2001/AC:2006	EN 556:1994 + A1:1998	Date expired (30.4.2002)
CEN	EN 556-2:2003 Sterilization of medical devices — Requirements for medical devices to be designated 'STERILE' — Part 2: Requirements for aseptically processed medical devices	—	
CEN	EN 591:2001 Instructions for use for *in vitro* diagnostic instruments for professional use	—	
CEN	EN 592:2002 Instructions for use for *in vitro* diagnostic instruments for self-testing	—	
CEN	EN 737-1:1998 Medical gas pipeline systems — Part 1: Terminal units for compressed medical gases and vacuum	—	
CEN	EN 737-4:1998 Medical gas pipeline systems — Part 4: Terminal units for anaesthetic gas scavenging systems	—	

ESO (1)	Reference and title of the harmonised standard (and reference document)	Reference of superseded standard	Date of cessation of presumption of conformity of superseded standard (Note 1)
CEN	EN 738-4:1998 Pressure regulators for use with medical gases — Part 4: Low-pressure regulators intended for incorporation into medical equipment	—	
	EN 738-4:1998/A1:2002	Note 3	Date expired (31.10.2002)
CEN	EN 739:1998 Low-pressure hose assemblies for use with medical gases	—	
	EN 739:1998/A1:2002	Note 3	Date expired (31.10.2002)
CEN	EN 794-1:1997 Lung ventilators — Part 1: Particular requirements for critical care ventilators	—	
	EN 794-1:1997/A1:2000	Note 3	Date expired (31.5.2001)
CEN	EN 794-3:1998 Lung ventilators — Part 3: Particular requirements for emergency and transport ventilators	—	
	EN 794-3:1998/A1:2005	Note 3	Date expired (31.12.2005)
CEN	EN 980:2003 Graphical symbols for use in the labelling of medical devices	EN 980:1996	Date expired (31.10.2003)
CEN	EN 1041:1998 Information supplied by the manufacturer with medical devices	—	
CEN	EN 1060-1:1995 Non-invasive sphygmomanometers — Part 1: General requirements	—	
	EN 1060-1:1995/A1:2002	Note 3	Date expired (30.11.2002)
CEN	EN 1060-2:1995 Non-invasive sphygmomanometers — Part 2: Supplementary requirements for mechanical sphygmomanometers	—	
CEN	EN 1060-3:1997 Non-invasive sphygmomanometers — Part 3: Supplementary requirements for electro-mechanical blood pressure measuring systems	—	
	EN 1060-3:1997/A1:2005	Note 3	Date expired (30.6.2006)
CEN	EN 1060-4:2004 Non-invasive sphygmomanometers — Part 4: Test procedures to determine the overall system accuracy of automated non-invasive sphygmomanometers	—	
CEN	EN 1089-3:2004 Transportable gas cylinders — Gas cylinder identification (excluding LPG) — Part 3: Colour coding	EN 1089-3:1997	Date expired (31.10.2004)
CEN	EN 1282-2:2005 Tracheostomy tubes — Part 2: Paediatric tubes (ISO 5366-3:2001, modified)	EN 1282-2:1997	Date expired (31.12.2005)
CEN	EN 1422:1997 Sterilizers for medical purposes — Ethylene oxide sterilizers — Requirements and test methods	—	

★ ここから

EN 1280-1 : 1997
EN 1280-1 : 1997/A1.2000 (delete)

Agent specific filling systems for anaesthetic vaporizers - Part 1 Rectangular keyed filling systems
(麻酔気化器の充てんシステム)
→ を削除
(EN ISO 5360 に置き換えられた)

ESO (1)	Reference and title of the harmonised standard (and reference document)	Reference of superseded standard	Date of cessation of presumption of conformity of superseded standard (Note 1)
CEN	EN 1618:1997 Catheters other than intravascular catheters — Test methods for common properties	—	
CEN	EN 1639:2004 Dentistry — Medical devices for dentistry — Instruments	EN 1639:1996	Date expired (31.12.2004)
CEN	EN 1640:2004 Dentistry — Medical devices for dentistry — Equipment	EN 1640:1996	Date expired (31.12.2004)
CEN	EN 1641:2004 Dentistry — Medical devices for dentistry — Materials	EN 1641:1996	Date expired (31.12.2004)
CEN	EN 1642:2004 Dentistry — Medical devices for dentistry — Dental implants	EN 1642:1996	Date expired (31.12.2004)
CEN	EN 1707:1996 Conical fittings with a 6 % (Luer) taper for syringes, needles and certain other medical equipment — Lock fittings	—	
CEN	EN 1782:1998 Tracheal tubes and connectors	—	
CEN	EN 1820:2005 Anaesthetic reservoir bags (ISO 5362:2000, modified)	EN 1820:1997	Date expired (31.12.2005)
CEN	EN 1865:1999 Specifications for stretchers and other patient handling equipment used in road ambulances	—	
CEN	EN 1970:2000 Adjustable beds for disabled persons — Requirements and test methods EN 1970:2000/A1:2005	— Note 3	 Date expired (30.9.2005)
CEN	EN 1985:1998 Walking aids — General requirements and test methods	—	
★ CEN	EN ISO 3826-3:2007 (ヒト血液と血液成分のためのプラスチック製折りたたみ式容器) Plastics collapsible containers for human blood and blood components — Part 3: Blood bag systems with integrated features (ISO 3826-3:2006)	—	★ 追加されました added
CEN	EN ISO 4074:2002 Natural latex rubber condoms — Requirements and test methods (ISO 4074:2002)	EN 600:1996	Date expired (31.8.2005)
CEN	EN ISO 4135:2001 Anaesthetic and respiratory equipment — Vocabulary (ISO 4135:2001)	EN ISO 4135:1996	Date expired (28.2.2002)
CEN	EN ISO 5356-1:2004 Anaesthetic and respiratory equipment — Conical connectors — Part 1: Cones and sockets (ISO 5356-1:2004)	EN 1281-1:1997	Date expired (30.11.2004)
CEN	EN ISO 5356-2:2007 Anaesthetic and respiratory equipment — Conical connectors — Part 2: Screw-threaded weight-bearing connectors (ISO 5356-2:2006)	EN 1281-2:1995	29.2.2008
★ CEN	EN ISO 5360:2007 (エアゾール化器の気化システム) Anaesthetic vaporizers — Agent-specific filling systems (ISO 5360:2006)	EN 1280-1:1997 (EN 1280-1 から置き換え) replaced	30.6.2008 ★ 追加されました added

ESO (1)	Reference and title of the harmonised standard (and reference document)	Reference of superseded standard	Date of cessation of presumption of conformity of superseded standard (Note 1)
CEN	EN ISO 5366-1:2004 Anaesthetic and respiratory equipment — Tracheostomy tubes — Part 1: Tubes and connectors for use in adults (ISO 5366-1:2000)	EN 1282-1:1996	Date expired (31.1.2005)
CEN	EN ISO 5840:2005 Cardiovascular implants — Cardiac valve prostheses (ISO 5840:2005)	EN 12006-1:1999	Date expired (30.6.2006)
CEN	EN ISO 7197:2006 Neurosurgical implants — Sterile, single-use hydrocephalus shunts and components (ISO 7197:2006)	—	
CEN	EN ISO 7376:2003 Anaesthetic and respiratory equipment — Laryngoscopes for tracheal intubation (ISO 7376:2003)	EN 1819:1997	Date expired (30.6.2004)
CEN	EN ISO 7396-1:2007 Medical gas pipeline systems — Part 1: Pipeline systems for compressed medical gases and vacuum (ISO 7396-1:2007)	EN 737-3:1998	30.4.2009
CEN	EN ISO 7396-2:2007 Medical gas pipeline systems — Part 2: Anaesthetic gas scavenging disposal systems (ISO 7396-2:2007)	EN 737-2:1998	30.4.2009
CEN	EN ISO 7439:2002 Copper-bearing intra-uterine contraceptive devices — Requirements, tests (ISO 7439:2002)	—	
CEN	EN ISO 7886-3:2005 Sterile hypodermic syringes for single use — Part 3: Auto-disable syringes for fixed-dose immunization (ISO 7886-3:2005)	—	
CEN	EN ISO 7886-4:2006 Sterile hypodermic syringes for single use — Part 4: Syringes with re-use prevention feature (ISO 7886-4:2006)	—	
CEN	EN ISO 8185:2007 Respiratory tract humidifiers for medical use — Particular requirements for respiratory humidification systems (ISO 8185:2007)	EN ISO 8185:1997	31.1.2008
CEN	EN ISO 8359:1996 Oxygen concentrators for medical use — Safety requirements (ISO 8359:1996)	—	
CEN	EN ISO 8536-4:2007 Infusion equipment for medical use — Part 4: Infusion sets for single use, gravity feed (ISO 8536-4:2007)	—	
CEN	EN ISO 8835-2:2007 Inhalational anaesthesia systems — Part 2: Anaesthetic breathing systems (ISO 8835-2:2007)	EN 740:1998	31.5.2009
CEN	EN ISO 8835-3:2007 Inhalational anaesthesia systems — Part 3: Transfer and receiving systems of active anaesthetic gas scavenging systems (ISO 8835-3:2007)	EN 740:1998	31.5.2009
CEN	EN ISO 8835-4:2004 Inhalational anaesthesia systems — Part 4: Anaesthetic vapour delivery devices (ISO 8835-4:2004) EN ISO 8835-4:2004/AC:2006	—	

ESO (1)	Reference and title of the harmonised standard (and reference document)	Reference of superseded standard	Date of cessation of presumption of conformity of superseded standard (Note 1)
CEN	EN ISO 8835-5:2004 Inhalational anaesthesia systems — Part 5: Anaesthesia ventilators (ISO 8835-5:2004) EN ISO 8835-5:2004/AC:2006	—	
CEN	EN ISO 9360-1:2000 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)	—	
CEN	EN ISO 9360-2:2002 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)	—	
CEN	EN ISO 9713:2004 Neurosurgical implants — Self-closing intracranial aneurysm clips (ISO 9713:2002)	—	
CEN	EN ISO 9919:2005 Medical electrical equipment — Particular requirements for the basic safety and essential performance of pulse oximeter equipment for medical use (ISO 9919:2005)	EN 865:1997	Date expired (30.9.2005)
CEN	EN ISO 10079-1:1999 Medical suction equipment — Part 1: Electrically powered suction equipment — Safety requirements (ISO 10079-1:1999)	EN ISO 10079-1:1996	Date expired (29.2.2000)
CEN	EN ISO 10079-2:1999 Medical suction equipment — Part 2: Manually powered suction equipment (ISO 10079-2:1999)	EN ISO 10079-2:1996	Date expired (29.2.2000)
CEN	EN ISO 10079-3:1999 Medical suction equipment — Part 3: Suction equipment powered from vacuum or pressure source (ISO 10079-3:1999)	EN ISO 10079-3:1996	Date expired (29.2.2000)
CEN	EN ISO 10328:2006 Prosthetics — Structural testing of lower-limb prostheses — Requirements and test methods (ISO 10328:2006)	—	
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)	EN 738-1:1997	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)	EN 738-2:1998	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)	EN 738-3:1998	31.10.2008
CEN	EN ISO 10535:2006 Hoists for the transfer of disabled persons — Requirements and test methods (ISO 10535:2006)	EN ISO 10535:1998	Date expired (30.6.2007)

ESO (1)	Reference and title of the harmonised standard (and reference document)	Reference of superseded standard	Date of cessation of presumption of conformity of superseded standard (Note 1)
CEN	EN ISO 10555-1:1996 Sterile, single-use intravascular catheters — Part 1: General requirements (ISO 10555-1:1995)	—	
	EN ISO 10555-1:1996/A1:1999	Note 3	Date expired (31.1.2000)
	EN ISO 10555-1:1996/A2:2004	Note 3	Date expired (30.11.2004)
CEN	EN ISO 10651-2:2004 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)	EN 794-2:1997	Date expired (31.1.2005)
CEN	EN ISO 10651-4:2002 Lung ventilators — Part 4: Particular requirements for operator-powered resuscitators (ISO 10651-4:2002)	—	
CEN	EN ISO 10651-6:2004 Lung ventilators for medical use — Particular requirements for basic safety and essential performance — Part 6: Home-care ventilatory support devices (ISO 10651-6:2004)	—	
CEN	EN ISO 10993-1:2003 Biological evaluation of medical devices — Part 1: Evaluation and testing (ISO 10993-1:2003)	—	
CEN	EN ISO 10993-3:2003 Biological evaluation of medical devices — Part 3: Tests for genotoxicity, carcinogenicity and reproductive toxicity (ISO 10993-3:2003)	EN 30993-3:1993	Date expired (30.4.2004)
CEN	EN ISO 10993-4:2002 Biological evaluation of medical devices — Part 4: Selection of tests for interactions with blood (ISO 10993-4:2002)	EN 30993-4:1993	Date expired (30.4.2003)
	EN ISO 10993-4:2002/A1:2006	Note 3	Date expired (31.1.2007)
CEN	EN ISO 10993-5:1999 Biological evaluation of medical devices — Part 5: Tests for *in vitro* cytotoxicity (ISO 10993-5:1999)	EN 30993-5:1994	Date expired (30.11.1999)
CEN	EN ISO 10993-6:2007 Biological evaluation of medical devices — Part 6: Tests for local effects after implantation (ISO 10993-6:2007)	EN 30993-6:1994	Date expired (31.10.2007)
CEN	EN ISO 10993-9:1999 Biological evaluation of medical devices — Part 9: Framework for identification and quantification of potential degradation products (ISO 10993-9:1999)	—	
CEN	EN ISO 10993-10:2002 Biological evaluation of medical devices — Part 10: Tests for irritation and delayed-type hypersensitivity (ISO 10993-10:2002)	EN ISO 10993-10:1995	Date expired (31.3.2003)
	EN ISO 10993-10:2002/A1:2006	Note 3	Date expired (31.1.2007)
CEN	EN ISO 10993-11:2006 Biological evaluation of medical devices — Part 11: Tests for systemic toxicity (ISO 10993-11:2006)	EN ISO 10993-11:1995	Date expired (28.2.2007)

ESO (1)	Reference and title of the harmonised standard (and reference document)	Reference of superseded standard	Date of cessation of presumption of conformity of superseded standard (Note 1)
CEN	EN ISO 10993-12:2007 Biological evaluation of medical devices — Part 12: Sample preparation and reference materials (ISO 10993-12:2007)	EN ISO 10993-12:2004	31.5.2008
CEN	EN ISO 10993-13:1998 Biological evaluation of medical devices — Part 13: Identification and quantification of degradation products from polymeric medical devices (ISO 10993-13:1998)	—	
CEN	EN ISO 10993-14:2001 Biological evaluation of medical devices — Part 14: Identification and quantification of degradation products from ceramics (ISO 10993-14:2001)	—	
CEN	EN ISO 10993-15:2000 Biological evaluation of medical devices — Part 15: Identification and quantification of degradation products from metals and alloys (ISO 10993-15:2000)	—	
CEN	EN ISO 10993-16:1997 Biological evaluation of medical devices — Part 16: Toxicokinetic study design for degradation products and leachables (ISO 10993-16:1997)	—	
CEN	EN ISO 10993-17:2002 Biological evaluation of medical devices — Part 17: Establishment of allowable limits for leachable substances (ISO 10993-17:2002)	—	
CEN	EN ISO 10993-18:2005 Biological evaluation of medical devices — Part 18: Chemical characterization of materials (ISO 10993-18:2005)	—	
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)	EN 550:1994	31.5.2010
CEN	EN ISO 11137-1:2006 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)	EN 552:1994	30.4.2009
CEN	EN ISO 11137-2:2007 Sterilization of health care products — Radiation — Part 2: Establishing the sterilization dose (ISO 11137-2:2006, corrected version 1.8.2006)	—	
CEN	EN ISO 11138-2:2006 Sterilization of health care products — Biological indicators — Part 2: Biological indicators for ethylene oxide sterilization processes (ISO 11138-2:2006)	—	
CEN	EN ISO 11138-3:2006 Sterilization of health care products — Biological indicators — Part 3: Biological indicators for moist heat sterilization processes (ISO 11138-3:2006)	—	
CEN	EN ISO 11140-1:2005 Sterilization of health care products — Chemical indicators — Part 1: General requirements (ISO 11140-1:2005)	EN 867-2:1997	Date expired (31.1.2006)
CEN	EN ISO 11140-3:2007 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)	EN 867-3:1997	Date expired (30.9.2007)

ESO (¹)	Reference and title of the harmonised standard (and reference document)	Reference of superseded standard	Date of cessation of presumption of conformity of superseded standard (Note 1)
CEN	EN ISO 11197:2004 Medical supply units (ISO 11197:2004)	EN 793:1997	Date expired (30.6.2005)
CEN	EN ISO 11607-1:2006 Packaging for terminally sterilized medical devices — Part 1: Requirements for materials, sterile barrier systems and packaging systems (ISO 11607-1:2006)	EN 868-1:1997	Date expired (30.4.2007)
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)	—	
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)	EN 1174-1:1996 EN 1174-2:1996 EN 1174-3:1996	Date expired (31.10.2006)
CEN	EN ISO 11810-2:2007 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)	—	
CEN	EN ISO 11979-8:2006 Ophthalmic implants — Intraocular lenses — Part 8: Fundamental requirements (ISO 11979-8:2006)	EN 13503-8:2000	Date expired (31.1.2007)
CEN	EN ISO 11990:2003 Optics and optical instruments — Lasers and laser-related equipment — Determination of laser resistance of tracheal tube shafts (ISO 11990:2003)	EN ISO 11990:1999	Date expired (31.10.2003)
CEN	EN 12006-2:1998 Non active surgical implants — Particular requirements for cardiac and vascular implants — Part 2: Vascular prostheses including cardiac valve conduits	—	
CEN	EN 12006-3:1998 Non active surgical implants — Particular requirements for cardiac and vascular implants — Part 3: Endovascular devices	—	
CEN	EN 12011:1998 Instrumentation to be used in association with non-active surgical implants — General requirements	—	
CEN	EN 12182:1999 Technical aids for disabled persons — General requirements and test methods	—	
CEN	EN 12322:1999 *In vitro* diagnostic medical devices — Culture media for microbiology — Performance criteria for culture media	—	
	EN 12322:1999/A1:2001	Note 3	Date expired (30.4.2002)
CEN	EN 12342:1998 Breathing tubes intended for use with anaesthetic apparatus and ventilators	—	
CEN	EN 12470-1:2000 Clinical thermometers — Part 1: Metallic liquid-in-glass thermometers with maximum device	—	

★ ここから

EN 12442-1:2000
EN 12442-2:2000
EN 12442-3:2000 を削除 delete
Animal tissues and their derivatives utilized in the manufacture of medical devices Part 1, Part 2, Part 3
(医療機器の製造に用いられる動物由来の組織・またはその抽出物)
(→ EN ISO 22442-1:2007に置き換え replaced.)

ESO (1)	Reference and title of the harmonised standard (and reference document)	Reference of superseded standard	Date of cessation of presumption of conformity of superseded standard (Note 1)
CEN	EN 12470-2:2000 Clinical thermometers — Part 2: Phase change type (dot matrix) thermometers	—	
CEN	EN 12470-3:2000 Clinical thermometers — Part 3: Performance of compact electrical thermometers (non-predictive and predictive) with maximum device	—	
CEN	EN 12470-4:2000 Clinical thermometers — Part 4: Performance of electrical thermometers for continuous measurement	—	
CEN	EN 12470-5:2003 Clinical thermometers — Part 5: Performance of infra-red ear thermometers (with maximum device)	—	
CEN	EN ISO 12870:2004 Ophthalmic optics — Spectacle frames — Requirements and test methods (ISO 12870:2004) EN ISO 12870:2004/AC:2005	EN ISO 12870:1997	Date expired (28.2.2005)
CEN	EN 13014:2000 Connections for gas sampling tubes to anaesthetic and respiratory equipment	—	
CEN	EN 13060:2004 Small steam sterilizers	—	
CEN	EN 13220:1998 Flow-metering devices for connection to terminal units of medical gas pipeline systems	—	
CEN	EN 13328-1:2001 Breathing system filters for anaesthetic and respiratory use — Part 1: Salt test method to assess filtration performance	—	
CEN	EN 13328-2:2002 Breathing system filters for anaesthetic and respiratory use — Part 2: Non-filtration aspects EN 13328-2:2002/A1:2003	— Note 3	 Date expired (30.6.2004)
CEN	EN ISO 13485:2003 Medical devices — Quality management systems — Requirements for regulatory purposes (ISO 13485:2003) EN ISO 13485:2003/AC:2007	EN ISO 13485:2000 EN ISO 13488:2000 EN 46003:1999	31.7.2009
CEN	EN 13544-1:2007 Respiratory therapy equipment — Part 1: Nebulizing systems and their components	EN 13544-1:2001	Date expired (31.10.2007)
CEN	EN 13544-2:2002 Respiratory therapy equipment — Part 2: Tubing and connectors	—	
CEN	EN 13544-3:2001 Respiratory therapy equipment — Part 3: Air entrainment devices	—	
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)	—	

ESO (1)	Reference and title of the harmonised standard (and reference document)	Reference of superseded standard	Date of cessation of presumption of conformity of superseded standard (Note 1)
CEN	EN 13718-1:2002 Air, water and difficult terrain ambulances — Part 1: Medical device interface requirements for the continuity of patient care	—	
CEN	EN 13726-1:2002 Test methods for primary wound dressings — Part 1: Aspects of absorbency	—	
CEN	EN 13726-2:2002 Test methods for primary wound dressings — Part 2: Moisture vapour transmission rate of permeable film dressings	—	
CEN	EN 13727:2003 Chemical disinfectants and antiseptics — Quantitative suspension test for the evaluation of bactericidal activity of chemical disinfectants for instruments used in the medical area — Test method and requirements (phase 2, step 1)	—	
CEN	EN 13795-1:2002 Surgical drapes, gowns and clean air suits, used as medical devices, for patients, clinical staff and equipment — Part 1: General requirements for manufacturers, processors and products	—	
CEN	EN 13795-2:2004 Surgical drapes, gowns and clean air suits, used as medical devices for patients, clinical staff and equipment — Part 2: Test methods	—	
CEN	EN 13795-3:2006 Surgical drapes, gowns and clean air suits, used as medical devices for patients, clinical staff and equipment — Part 3: Performance requirements and performance levels	—	
CEN	EN 13824:2004 Sterilization of medical devices — Aseptic processing of liquid medical devices — Requirements	—	
CEN	EN 13867:2002 Concentrates for haemodialysis and related therapies	—	
CEN	EN 13976-1:2003 Rescue systems — Transportation of incubators — Part 1: Interface conditions	—	
CEN	EN 13976-2:2003 Rescue systems — Transportation of incubators — Part 2: System requirements	—	
CEN	EN 14079:2003 Non-active medical devices — Performance requirements and test methods for absorbent cotton gauze and absorbent cotton and viscose gauze	—	
CEN	EN ISO 14155-1:2003 Clinical investigation of medical devices for human subjects — Part 1: General requirements (ISO 14155-1:2003)	EN 540:1993	Date expired (31.8.2003)
CEN	EN ISO 14155-2:2003 Clinical investigation of medical devices for human subjects — Part 2: Clinical investigation plans (ISO 14155-2:2003)	—	
CEN	EN ISO 14160:1998 Sterilization of single-use medical devices incorporating materials of animal origin — Validation and routine control of sterilization by liquid chemical sterilants (ISO 14160:1998)	—	

ESO (1)	Reference and title of the harmonised standard (and reference document)	Reference of superseded standard	Date of cessation of presumption of conformity of superseded standard (Note 1)
CEN	EN 14180:2003 Sterilizers for medical purposes — Low temperature steam and formaldehyde sterilizers — Requirements and testing	—	
CEN	EN 14299:2004 Non active surgical implants — Particular requirements for cardiac and vascular implants — Specific requirements for arterial stents	—	
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)	—	
CEN	EN ISO 14408:2005 Tracheal tubes designed for laser surgery — Requirements for marking and accompanying information (ISO 14408:2005)	—	
CEN	EN ISO 14534:2002 Ophthalmic optics — Contact lenses and contact lens care products — Fundamental requirements (ISO 14534:2002)	EN ISO 14534:1997	Date expired (31.12.2002)
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)	—	
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)	—	
CEN	EN ISO 14602:1998 Non-active surgical implants — Implants for Osteosynthesis — Particular requirements (ISO 14602:1998)	—	
CEN	EN ISO 14607:2007 Non-active surgical implants — Mammary implants — Particular requirements (ISO 14607:2007)	—	
CEN	EN ISO 14630:2005 Non-active surgical implants — General requirements (ISO 14630:2005)	EN ISO 14630:1997	Date expired (30.11.2005)
CEN	EN 14683:2005 Surgical masks — Requirements and test methods	—	
CEN	EN ISO 14889:2003 Ophthalmic optics — Spectacle lenses — Fundamental requirements for uncut finished lenses (ISO 14889:2003)	EN ISO 14889:1997	Date expired (30.11.2003)
CEN	EN 14931:2006 Pressure vessels for human occupancy (PVHO) — Multi-place pressure chamber systems for hyperbaric therapy — Performance, safety requirements and testing	—	
CEN	EN ISO 14937:2000 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 14937:2000)	—	

ESO (1)	Reference and title of the harmonised standard (and reference document)	Reference of superseded standard	Date of cessation of presumption of conformity of superseded standard (Note 1)
CEN	EN ISO 14971:2007 Medical devices — Application of risk management to medical devices (ISO 14971:2007)	EN ISO 14971:2000	31.3.2010
CEN	EN ISO 15001:2004 Anaesthetic and respiratory equipment — Compatibility with oxygen (ISO 15001:2003)	—	
CEN	EN ISO 15004-1:2006 Ophthalmic instruments — Fundamental requirements and test methods — Part 1: General requirements applicable to all ophthalmic instruments (ISO 15004-1:2006)	EN ISO 15004:1997	Date expired (31.12.2006)
CEN	EN ISO 15225:2000 Nomenclature — Specification for a nomenclature system for medical devices for the purpose of regulatory data exchange (ISO 15225:2000) EN ISO 15225:2000/A1:2004	— Note 3	 Date expired (31.8.2004)
CEN	EN 15424:2007 Sterilization of medical devices — Low temperature steam and formaldehyde — Requirements for development, validation and routine control of a sterilization process for medical devices	—	
CEN	EN ISO 15747:2005 Plastics containers for intravenous injection (ISO 15747:2003)	—	
CEN	EN ISO 15883-1:2006 Washer-disinfectors — Part 1: General requirements, terms and definitions and tests (ISO 15883-1:2006)	—	
CEN	EN ISO 15883-2:2006 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)	—	
CEN	EN ISO 15883-3:2006 Washer-disinfectors — Part 3: Requirements and tests for washer-disinfectors employing thermal disinfection for human waste containers (ISO 15883-3:2006)	—	
CEN	EN ISO 16201:2006 Technical aids for disabled persons — Environmental control systems for daily living (ISO 16201:2006)	—	
★ CEN	EN ISO 17510-1:2007 (無呼吸睡眠症候群) Sleep apnoea breathing therapy — Part 1: Sleep apnoea breathing therapy equipment (ISO 17510-1:2007)	EN ISO 17510-1:2002	30.4.2008 ★追加 added
★ CEN	EN ISO 17510-2:2007 Sleep apnoea breathing therapy — Part 2: Masks and application accessories (ISO 17510-2:2007)	EN ISO 17510-2:2003	30.4.2008 ★追加 added
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)	—	
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)	EN 554:1994	31.8.2009

ESO (1)	Reference and title of the harmonised standard (and reference document)	Reference of superseded standard	Date of cessation of presumption of conformity of superseded standard (Note 1)
CEN	EN ISO 18777:2005 Transportable liquid oxygen systems for medical use — Particular requirements (ISO 18777:2005)	—	
CEN	EN ISO 18778:2005 Respiratory equipment — Infant monitors — Particular requirements (ISO 18778:2005)	—	
CEN	EN ISO 18779:2005 Medical devices for conserving oxygen and oxygen mixtures — Particular requirements (ISO 18779:2005)	—	
CEN	EN ISO 19054:2006 Rail systems for supporting medical equipment (ISO 19054:2005)	EN 12218:1998	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) EN 20594-1:1993/A1:1997	— Note 3	 Date expired (31.5.1998)
CEN	EN ISO 21171:2006 Medical gloves — Determination of removable surface powder (ISO 21171:2006)	—	
CEN	EN ISO 21534:2007 Non-active surgical implants — Joint replacement implants — Particular requirements (ISO 21534:2007)	EN 12010:1998	31.3.2008
CEN	EN ISO 21535:2007 Non-active surgical implants — Joint replacement implants — Specific requirements for hip-joint replacement implants (ISO 21535:2007)	EN 12563:1998	31.3.2008
CEN	EN ISO 21536:2007 Non-active surgical implants — Joint replacement implants — Specific requirements for knee-joint replacement implants (ISO 21536:2007)	EN 12564:1998	31.3.2008
CEN	EN ISO 21647:2004 Medical electrical equipment — Particular requirements for the basic safety and essential performance of respiratory gas monitors (ISO 21647:2004) EN ISO 21647:2004/AC:2006	EN 12598:1999 EN 864:1996 EN ISO 11196:1997	Date expired (31.5.2005)
CEN	EN ISO 21649:2006 Needle-free injectors for medical use — Requirements and test methods (ISO 21649:2006)	—	
CEN	EN ISO 21969:2006 High-pressure flexible connections for use with medical gas systems (ISO 21969:2005)	EN 13221:2000	Date expired (31.12.2007)
★ CEN	EN ISO 22442-1:2007 (動物由来の組織またはその相生物を用いた医療機器) Medical devices utilizing animal tissues and their derivatives — Part 1: Application of risk management (ISO 22442-1:2007)	EN 12442-1:2000	30.6.2008 ★ 也加 added
★ 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)	EN 12442-2:2000	30.6.2008 ★ 也加 added
★ 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)	EN 12442-3:2000	30.6.2008 ★ 也加 added

→ EN 12442-1, 2, 3 も 置き換え.

ESO (1)	Reference and title of the harmonised standard (and reference document)	Reference of superseded standard	Date of cessation of presumption of conformity of superseded standard (Note 1)
CEN	EN ISO 22523:2006 External limb prostheses and external orthoses — Requirements and test methods (ISO 22523:2006)	EN 12523:1999	Date expired (30.4.2007)
CEN	EN ISO 22610:2006 Surgical drapes, gowns and clean air suits, used as medical devices, for patients, clinical staff and equipment — Test method to determine the resistance to wet bacterial penetration (ISO 22610:2006)	—	
CEN	EN ISO 22612:2005 Clothing for protection against infectious agents — Test method for resistance to dry microbial penetration (ISO 22612:2005)	—	
CEN	EN ISO 22675:2006 Prosthetics — Testing of ankle-foot devices and foot units — Requirements and test methods (ISO 22675:2006)	—	
CEN	EN ISO 23747:2007 Anaesthetic and respiratory equipment — Peak expiratory flow meters for the assessment of pulmonary function in spontaneously breathing humans (ISO 23747:2007)	EN 13826:2003	31.1.2008
CEN	EN 27740:1992 Instruments for surgery, scalpels with detachable blades, fitting dimensions (ISO 7740:1985)	—	
	EN 27740:1992/A1:1997	Note 3	Date expired (31.5.1998)

(1) ESO: European Standardisation Organisation:
— CEN: rue de Stassart 36, B-1050 Brussels, Tel. (32-2) 550 08 11; fax (32-2) 550 08 19 (http://www.cen.eu)
— CENELEC: rue de Stassart 35, B-1050 Brussels, Tel. (32-2) 519 68 71; fax (32-2) 519 69 19 (http://www.cenelec.org)
— ETSI: 650, route des Lucioles, F-06921 Sophia Antipolis, Tel. (33) 492 94 42 00; fax (33) 493 65 47 16 (http://www.etsi.org).

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 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 (column 3) 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 requirements of the directive.

NOTE:

— Any information concerning the availability of the standards can be obtained either from the European Standardisation Organisations or from the national standardisation bodies of which the list is annexed to the Directive 98/34/EC of the European Parliament and of the Council (1) amended by the Directive 98/48/EC (2).

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

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

More information about harmonised standards on the Internet at:
http://ec.europa.eu/enterprise/newapproach/standardization/harmstds/

(1) OJ L 204, 21.7.1998, p. 37.
(2) OJ L 217, 5.8.1998, p. 18.