# NOTICES FROM MEMBER STATES

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

**(Text with EEA relevance)**

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

(2008/C 186/07)

| ESO (1) | Reference and title of the harmonised standard (and reference document) | Reference of superseded standard | Date of cessation of presumption of conformity of superseded standard (Note 1) |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 375:2001<br>Information supplied by the manufacturer with *in vitro* diagnostic reagents for professional use | — | |
| CEN | EN 376:2002<br>Information supplied by the manufacturer with *in vitro* diagnostic reagents for self-testing | — | |
| CEN | EN 455-1:2000<br>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<br>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<br>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<br>Sterilization of medical devices — Requirements for medical devices to be designated 'STERILE' — Part 1: Requirements for terminally sterilized medical devices | EN 556:1994 + A1:1998 | Date expired (30.4.2002) |
| | EN 556-1:2001/AC:2006 | | |
| CEN | EN 556-2:2003<br>Sterilization of medical devices — Requirements for medical devices to be designated 'STERILE' — Part 2: Requirements for aseptically processed medical devices | — | |
| CEN | EN 591:2001<br>Instructions for use for *in vitro* diagnostic instruments for professional use | — | |
| CEN | EN 592:2002<br>Instructions for use for *in vitro* diagnostic instruments for self-testing | — | |

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| CEN | EN 737-1:1998<br>Medical gas pipeline systems — Part 1: Terminal units for compressed medical gases and vacuum | — | |
| CEN | EN 737-4:1998<br>Medical gas pipeline systems — Part 4: Terminal units for anaesthetic gas scavenging systems | — | |
| CEN | EN 794-1:1997<br>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<br>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 980:2008<br>Symbols for use in the labelling of medical devices | EN 980:2003 | 31.5.2010 |
| CEN | EN 1041:1998<br>Information supplied by the manufacturer with medical devices | — | |
| CEN | EN 1060-1:1995<br>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<br>Non-invasive sphygmomanometers — Part 2: Supplementary requirements for mechanical sphygmomanometers | — | |
| CEN | EN 1060-3:1997<br>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<br>Non-invasive sphygmomanometers — Part 4: Test procedures to determine the overall system accuracy of automated non-invasive sphygmomanometers | — | |
| CEN | EN 1089-3:2004<br>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<br>Tracheostomy tubes — Part 2: Paediatric tubes (ISO 5366-3:2001, modified) | EN 1282-2:1997 | Date expired (31.12.2005) |
| CEN | EN 1422:1997<br>Sterilizers for medical purposes — Ethylene oxide sterilizers — Requirements and test methods | — | |

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| CEN | EN 1618:1997<br>Catheters other than intravascular catheters — Test methods for common properties | — | |
| CEN | EN 1639:2004<br>Dentistry — Medical devices for dentistry — Instruments | EN 1639:1996 | Date expired (31.12.2004) |
| CEN | EN 1640:2004<br>Dentistry — Medical devices for dentistry — Equipment | EN 1640:1996 | Date expired (31.12.2004) |
| CEN | EN 1641:2004<br>Dentistry — Medical devices for dentistry — Materials | EN 1641:1996 | Date expired (31.12.2004) |
| CEN | EN 1642:2004<br>Dentistry — Medical devices for dentistry — Dental implants | EN 1642:1996 | Date expired (31.12.2004) |
| CEN | EN 1707:1996<br>Conical fittings with a 6 % (Luer) taper for syringes, needles and certain other medical equipment — Lock fittings | — | |
| CEN | EN 1782:1998<br>Tracheal tubes and connectors | — | |
| CEN | EN 1789:2007<br>Medical vehicles and their equipment — Road ambulances | EN 1789:1999 | Date expired (30.11.2007) |
| CEN | EN 1820:2005<br>Anaesthetic reservoir bags (ISO 5362:2000, modified) | EN 1820:1997 | Date expired (31.12.2005) |
| CEN | EN 1865:1999<br>Specifications for stretchers and other patient handling equipment used in road ambulances | — | |
| CEN | EN 1970:2000<br>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<br>Walking aids — General requirements and test methods | — | |
| CEN | EN ISO 3826-3:2007<br>Plastics collapsible containers for human blood and blood components — Part 3: Blood bag systems with integrated features (ISO 3826-3:2006) | — | |
| CEN | EN ISO 4074:2002<br>Natural latex rubber condoms — Requirements and test methods (ISO 4074:2002) | EN 600:1996 | Date expired (31.8.2005) |
| CEN | EN ISO 4135:2001<br>Anaesthetic and respiratory equipment — Vocabulary (ISO 4135:2001) | EN ISO 4135:1996 | Date expired (28.2.2002) |

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| CEN | EN ISO 5356-1:2004<br>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<br>Anaesthetic and respiratory equipment — Conical connectors — Part 2: Screw-threaded weight-bearing connectors (ISO 5356-2:2006) | EN 1281-2:1995 | Date expired (29.2.2008) |
| CEN | EN ISO 5359:2008<br>Low-pressure hose assemblies for use with medical gases (ISO 5359:2008) | EN 739:1998 | 30.6.2010 |
| CEN | EN ISO 5360:2007<br>Anaesthetic vaporizers — Agent-specific filling systems (ISO 5360:2006) | EN 1280-1:1997 | Date expired (30.6.2008) |
| CEN | EN ISO 5366-1:2004<br>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<br>Cardiovascular implants — Cardiac valve prostheses (ISO 5840:2005) | EN 12006-1:1999 | Date expired (30.6.2006) |
| CEN | EN ISO 7197:2006<br>Neurosurgical implants — Sterile, single-use hydrocephalus shunts and components (ISO 7197:2006) | — | |
| CEN | EN ISO 7376:2003<br>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<br>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<br>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<br>Copper-bearing intra-uterine contraceptive devices — Requirements, tests (ISO 7439:2002) | — | |
| CEN | EN ISO 7886-3:2005<br>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<br>Sterile hypodermic syringes for single use — Part 4: Syringes with re-use prevention feature (ISO 7886-4:2006) | — | |
| CEN | EN ISO 8185:2007<br>Respiratory tract humidifiers for medical use — Particular requirements for respiratory humidification systems (ISO 8185:2007) | EN ISO 8185:1997 | Date expired (31.1.2008) |

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| CEN | EN ISO 8359:1996<br>Oxygen concentrators for medical use — Safety requirements (ISO 8359:1996) | — | |
| CEN | EN ISO 8536-4:2007<br>Infusion equipment for medical use — Part 4: Infusion sets for single use, gravity feed (ISO 8536-4:2007) | — | |
| CEN | EN ISO 8835-2:2007<br>Inhalational anaesthesia systems — Part 2: Anaesthetic breathing systems (ISO 8835-2:2007) | EN 740:1998 | 31.5.2009 |
| CEN | EN ISO 8835-3:2007<br>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<br>Inhalational anaesthesia systems — Part 4: Anaesthetic vapour delivery devices (ISO 8835-4:2004) | — | |
| | EN ISO 8835-4:2004/AC:2006 | | |
| CEN | EN ISO 8835-5:2004<br>Inhalational anaesthesia systems — Part 5: Anaesthesia ventilators (ISO 8835-5:2004) | — | |
| | EN ISO 8835-5:2004/AC:2006 | | |
| CEN | EN ISO 9360-1:2000<br>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<br>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<br>Neurosurgical implants — Self-closing intracranial aneurysm clips (ISO 9713:2002) | — | |
| CEN | EN ISO 9919:2005<br>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<br>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<br>Medical suction equipment — Part 2: Manually powered suction equipment (ISO 10079-2:1999) | EN ISO 10079-2:1996 | Date expired (29.2.2000) |

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| CEN | EN ISO 10079-3:1999<br>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<br>Prosthetics — Structural testing of lower-limb prostheses — Requirements and test methods (ISO 10328:2006) | — | |
| CEN | EN ISO 10524-1:2006<br>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<br>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<br>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 10524-4:2008<br>Pressure regulators for use with medical gases — Part 4: Low-pressure regulators (ISO 10524-4:2008) | EN 738-4:1998 | 30.6.2010 |
| CEN | EN ISO 10535:2006<br>Hoists for the transfer of disabled persons — Requirements and test methods (ISO 10535:2006) | EN ISO 10535:1998 | Date expired (30.6.2007) |
| CEN | EN ISO 10555-1:1996<br>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<br>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<br>Lung ventilators — Part 4: Particular requirements for operator-powered resuscitators (ISO 10651-4:2002) | — | |
| CEN | EN ISO 10651-6:2004<br>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<br>Biological evaluation of medical devices — Part 1: Evaluation and testing (ISO 10993-1:2003) | — | |

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| CEN | EN ISO 10993-3:2003<br>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<br>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<br>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<br>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<br>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<br>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<br>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) |
| CEN | EN ISO 10993-12:2007<br>Biological evaluation of medical devices — Part 12: Sample preparation and reference materials (ISO 10993-12:2007) | EN ISO 10993-12:2004 | Date expired (31.5.2008) |
| CEN | EN ISO 10993-13:1998<br>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<br>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<br>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<br>Biological evaluation of medical devices — Part 16: Toxicokinetic study design for degradation products and leachables (ISO 10993-16:1997) | — | |

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| CEN | EN ISO 10993-17:2002<br>Biological evaluation of medical devices — Part 17: Establishment of allowable limits for leachable substances (ISO 10993-17:2002) | — | |
| CEN | EN ISO 10993-18:2005<br>Biological evaluation of medical devices — Part 18: Chemical characterization of materials (ISO 10993-18:2005) | — | |
| CEN | EN ISO 11135-1:2007<br>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<br>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<br>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<br>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<br>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<br>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<br>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) |
| CEN | EN ISO 11197:2004<br>Medical supply units (ISO 11197:2004) | EN 793:1997 | Date expired (30.6.2005) |
| CEN | EN ISO 11607-1:2006<br>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<br>Packaging for terminally sterilized medical devices — Part 2: Validation requirements for forming, sealing and assembly processes (ISO 11607-2:2006) | — | |

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| CEN | EN ISO 11737-1:2006<br>Sterilization of medical devices — Microbiological methods — Part 1: Determination of a population of microorganisms on products (ISO 11737-1:2006) | EN 1174-1:1996<br>EN 1174-2:1996<br>EN 1174-3:1996 | Date expired (31.10.2006) |
| CEN | EN ISO 11810-2:2007<br>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<br>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<br>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<br>Non active surgical implants — Particular requirements for cardiac and vascular implants — Part 2: Vascular prostheses including cardiac valve conduits | — | |
| CEN | EN 12006-3:1998<br>Non active surgical implants — Particular requirements for cardiac and vascular implants — Part 3: Endovascular devices | — | |
| CEN | EN 12011:1998<br>Instrumentation to be used in association with non-active surgical implants — General requirements | — | |
| CEN | EN 12182:1999<br>Technical aids for disabled persons — General requirements and test methods | — | |
| CEN | EN 12322:1999<br>*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<br>Breathing tubes intended for use with anaesthetic apparatus and ventilators | — | |
| CEN | EN 12470-1:2000<br>Clinical thermometers — Part 1: Metallic liquid-in-glass thermometers with maximum device | — | |
| CEN | EN 12470-2:2000<br>Clinical thermometers — Part 2: Phase change type (dot matrix) thermometers | — | |

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| CEN | EN 12470-3:2000<br>Clinical thermometers — Part 3: Performance of compact electrical thermometers (non-predictive and predictive) with maximum device | — | |
| CEN | EN 12470-4:2000<br>Clinical thermometers — Part 4: Performance of electrical thermometers for continuous measurement | — | |
| CEN | EN 12470-5:2003<br>Clinical thermometers — Part 5: Performance of infra-red ear thermometers (with maximum device) | — | |
| CEN | EN ISO 12870:2004<br>Ophthalmic optics — Spectacle frames — Requirements and test methods (ISO 12870:2004) | EN ISO 12870:1997 | Date expired (28.2.2005) |
| | EN ISO 12870:2004/AC:2005 | | |
| CEN | EN 13014:2000<br>Connections for gas sampling tubes to anaesthetic and respiratory equipment | — | |
| CEN | EN 13060:2004<br>Small steam sterilizers | — | |
| CEN | EN 13220:1998<br>Flow-metering devices for connection to terminal units of medical gas pipeline systems | — | |
| CEN | EN ISO 13485:2003<br>Medical devices — Quality management systems — Requirements for regulatory purposes (ISO 13485:2003) | EN 46003:1999<br>EN ISO 13485:2000<br>EN ISO 13488:2000 | 31.7.2009 |
| | EN ISO 13485:2003/AC:2007 | | |
| CEN | EN 13544-1:2007<br>Respiratory therapy equipment — Part 1: Nebulizing systems and their components | EN 13544-1:2001 | Date expired (31.10.2007) |
| CEN | EN 13544-2:2002<br>Respiratory therapy equipment — Part 2: Tubing and connectors | — | |
| CEN | EN 13544-3:2001<br>Respiratory therapy equipment — Part 3: Air entrainment devices | — | |
| CEN | EN 13624:2003<br>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) | — | |
| CEN | EN 13718-1:2002<br>Air, water and difficult terrain ambulances — Part 1: Medical device interface requirements for the continuity of patient care | — | |
| CEN | EN 13726-1:2002<br>Test methods for primary wound dressings — Part 1: Aspects of absorbency | — | |

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| CEN | EN 13726-2:2002<br>Test methods for primary wound dressings — Part 2: Moisture vapour transmission rate of permeable film dressings | — | |
| CEN | EN 13727:2003<br>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 13824:2004<br>Sterilization of medical devices — Aseptic processing of liquid medical devices — Requirements | — | |
| CEN | EN 13867:2002<br>Concentrates for haemodialysis and related therapies | — | |
| CEN | EN 13976-1:2003<br>Rescue systems — Transportation of incubators — Part 1: Interface conditions | — | |
| CEN | EN 13976-2:2003<br>Rescue systems — Transportation of incubators — Part 2: System requirements | — | |
| CEN | EN 14079:2003<br>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<br>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<br>Clinical investigation of medical devices for human subjects — Part 2: Clinical investigation plans (ISO 14155-2:2003) | — | |
| CEN | EN ISO 14160:1998<br>Sterilization of single-use medical devices incorporating materials of animal origin — Validation and routine control of sterilization by liquid chemical sterilants (ISO 14160:1998) | — | |
| CEN | EN 14180:2003<br>Sterilizers for medical purposes — Low temperature steam and formaldehyde sterilizers — Requirements and testing | — | |
| CEN | EN 14299:2004<br>Non active surgical implants — Particular requirements for cardiac and vascular implants — Specific requirements for arterial stents | — | |
| CEN | EN 14348:2005<br>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) | — | |

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| CEN | EN ISO 14408:2005<br>Tracheal tubes designed for laser surgery — Requirements for marking and accompanying information (ISO 14408:2005) | — | |
| CEN | EN ISO 14534:2002<br>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<br>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<br>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<br>Non-active surgical implants — Implants for Osteosynthesis — Particular requirements (ISO 14602:1998) | — | |
| CEN | EN ISO 14607:2007<br>Non-active surgical implants — Mammary implants — Particular requirements (ISO 14607:2007) | — | |
| CEN | EN ISO 14630:2008<br>Non-active surgical implants — General requirements (ISO 14630:2008) | EN ISO 14630:2005 | 31.7.2008 |
| CEN | EN 14683:2005<br>Surgical masks — Requirements and test methods | — | |
| CEN | EN ISO 14889:2003<br>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<br>Pressure vessels for human occupancy (PVHO) — Multi-place pressure chamber systems for hyperbaric therapy — Performance, safety requirements and testing | — | |
| CEN | EN ISO 14937:2000<br>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) | — | |
| CEN | EN ISO 14971:2007<br>Medical devices — Application of risk management to medical devices (ISO 14971:2007) | EN ISO 14971:2000 | 31.3.2010 |
| CEN | EN ISO 15001:2004<br>Anaesthetic and respiratory equipment — Compatibility with oxygen (ISO 15001:2003) | — | |

| 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 15004-1:2006<br>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<br>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<br>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 15546-1:2008<br>Small bore connectors for liquids and gases in healthcare applications — Part 1 — General Requirements | — | |
| CEN | EN ISO 15747:2005<br>Plastics containers for intravenous injection (ISO 15747:2003) | — | |
| CEN | EN ISO 15883-1:2006<br>Washer-disinfectors — Part 1: General requirements, terms and definitions and tests (ISO 15883-1:2006) | — | |
| CEN | EN ISO 15883-2:2006<br>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<br>Washer-disinfectors — Part 3: Requirements and tests for washer-disinfectors employing thermal disinfection for human waste containers (ISO 15883-3:2006) | — | |
| CEN | EN ISO 15883-4:2008<br>Washer-disinfectors — Part 4: Requirements and tests for washer-disinfectors employing chemical disinfection for thermolabile endoscopes (ISO 15883-4:2008) | — | |
| CEN | EN ISO 16201:2006<br>Technical aids for disabled persons — Environmental control systems for daily living (ISO 16201:2006) | — | |
| CEN | EN ISO 17510-1:2007<br>Sleep apnoea breathing therapy — Part 1: Sleep apnoea breathing therapy equipment (ISO 17510-1:2007) | EN ISO 17510-1:2002 | Date expired (30.4.2008) |
| CEN | EN ISO 17510-2:2007<br>Sleep apnoea breathing therapy — Part 2: Masks and application accessories (ISO 17510-2:2007) | EN ISO 17510-2:2003 | Date expired (30.4.2008) |

| 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 17664:2004<br>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<br>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 |
| CEN | EN ISO 18777:2005<br>Transportable liquid oxygen systems for medical use — Particular requirements (ISO 18777:2005) | — | |
| CEN | EN ISO 18778:2005<br>Respiratory equipment — Infant monitors — Particular requirements (ISO 18778:2005) | — | |
| CEN | EN ISO 18779:2005<br>Medical devices for conserving oxygen and oxygen mixtures — Particular requirements (ISO 18779:2005) | — | |
| CEN | EN ISO 19054:2006<br>Rail systems for supporting medical equipment (ISO 19054:2005) | EN 12218:1998 | Date expired (30.6.2008) |
| CEN | EN 20594-1:1993<br>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<br>Medical gloves — Determination of removable surface powder (ISO 21171:2006) | — | |
| CEN | EN ISO 21534:2007<br>Non-active surgical implants — Joint replacement implants — Particular requirements (ISO 21534:2007) | EN 12010:1998 | Date expired (31.3.2008) |
| CEN | EN ISO 21535:2007<br>Non-active surgical implants — Joint replacement implants — Specific requirements for hip-joint replacement implants (ISO 21535:2007) | EN 12563:1998 | Date expired (31.3.2008) |
| CEN | EN ISO 21536:2007<br>Non-active surgical implants — Joint replacement implants — Specific requirements for knee-joint replacement implants (ISO 21536:2007) | EN 12564:1998 | Date expired (31.3.2008) |
| CEN | EN ISO 21647:2004<br>Medical electrical equipment — Particular requirements for the basic safety and essential performance of respiratory gas monitors (ISO 21647:2004) | EN 12598:1999<br>EN 864:1996<br>EN ISO 11196:1997 | Date expired (31.5.2005) |
| | EN ISO 21647:2004/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 21649:2006<br>Needle-free injectors for medical use — Requirements and test methods (ISO 21649:2006) | — | |
| CEN | EN ISO 21969:2006<br>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<br>Medical devices utilizing animal tissues and their derivatives — Part 1: Application of risk management (ISO 22442-1:2007) | EN 12442-1:2000 | Date expired (30.6.2008) |
| CEN | EN ISO 22442-2:2007<br>Medical devices utilizing animal tissues and their derivatives — Part 2: Controls on sourcing, collection and handling (ISO 22442-2:2007) | EN 12442-2:2000 | Date expired (30.6.2008) |
| CEN | EN ISO 22442-3:2007<br>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 | Date expired (30.6.2008) |
| CEN | EN ISO 22523:2006<br>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<br>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<br>Clothing for protection against infectious agents — Test method for resistance to dry microbial penetration (ISO 22612:2005) | — | |
| CEN | EN ISO 22675:2006<br>Prosthetics — Testing of ankle-foot devices and foot units — Requirements and test methods (ISO 22675:2006) | — | |
| CEN | EN ISO 23328-1:2008<br>Breathing system filters for anaesthetic and respiratory use — Part 1: Salt test method to assess filtration performance (ISO 23328-1:2003) | EN 13328-1:2001 | 30.9.2008 |
| CEN | EN ISO 23328-2:2008<br>Breathing system filters for anaesthetic and respiratory use — Part 2: Non-filtration aspects (ISO 23328-2:2002) | EN 13328-2:2002 | 30.9.2008 |
| CEN | EN ISO 23747:2007<br>Anaesthetic and respiratory equipment — Peak expiratory flow meters for the assessment of pulmonary function in spontaneously breathing humans (ISO 23747:2007) | EN 13826:2003 | Date expired (31.1.2008) |

| 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 27740:1992<br>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.