

**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 harmonized standards under the directive)

(2008/C 304/06)

ESO ⁽¹⁾	Reference and title of the standard (and reference document)	Reference of the superseded standard	Date of cessation of presumption of conformity of the superseded standard (Note 1)
Cenelec	EN 60118-13:2005 Electroacoustics — Hearing aids — Part 13: Electromagnetic compatibility (EMC) (IEC 60118-13:2004)	EN 60118-13:1997 Note 2.1	Date expired (1.2.2008)
Cenelec	EN 60522:1999 Determination of the permanent filtration of X-ray tube assemblies (IEC 60522:1999)	—	—
Cenelec	EN 60580:2000 Medical electrical equipment — Dose area product meters (IEC 60580:2000)	—	—
Cenelec	EN 60601-1:1990 Medical electrical equipment — Part 1: General requirements for safety (IEC 60601-1:1988)	—	—
	Amendment A1:1993 to EN 60601-1:1990 (IEC 60601-1:1988/A1:1991)	Note 3	—
	Amendment A2:1995 to EN 60601-1:1990 (IEC 60601-1:1988/A2:1995)	Note 3	—
Cenelec	EN 60601-1:2006 Medical electrical equipment — Part 1: General requirements for basic safety and essential performance (IEC 60601-1:2005)	EN 60601-1:1990 and its amendments Note 2.1	—
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)	EN 60601-1-1:1993 + A1:1996 Note 2.1	Date expired (1.12.2003)
Cenelec	EN 60601-1-2:2001 Medical electrical equipment — Part 1-2: General requirements for safety — Collateral standard: Electromagnetic compatibility — Requirements and tests (IEC 60601-1-2:2001)	EN 60601-1-2:1993 Note 2.1	Date expired (1.11.2004)
	Amendment A1:2006 to EN 60601-1-2:2001 (IEC 60601-1-2:2001/A1:2004)	—	1.3.2009
Cenelec	EN 60601-1-2:2007 Medical electrical equipment — Part 1-2: General requirements for basic safety and essential performance — Collateral standard: Electromagnetic compatibility — Requirements and tests (IEC 60601-1-2:2007 (Modified))	EN 60601-1-2:2001 and its amendment Note 2.1	—

ESO (*)	Reference and title of the standard (and reference document)	Reference of the superseded standard	Date of cessation of presumption of conformity of the superseded standard (Note 1)
Cenelec	EN 60601-1-3:1994 Medical electrical equipment — Part 1: General requirements for safety — Collateral standard: General requirements for radiation protection in diagnostic X-ray equipment (IEC 60601-1-3:1994)	—	—
Cenelec	EN 60601-1-3:2008 Medical electrical equipment — Part 1-3: General requirements for basic safety and essential performance — Collateral standard: Radiation protec- tion in diagnostic X-ray equipment (IEC 60601-1-3:2008)	EN 60601-1-3:1994 Note 2.1	—
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)	—	—
	Amendment A1:1999 to EN 60601-1-4:1996 (IEC 60601-1-4:1996/A1:1999)	Note 3	Date expired (1.12.2002)
Cenelec	EN 60601-1-6:2004 Medical electrical equipment — Part 1-6: General requirements for safety — Collateral standard: Usability (IEC 60601-1-6:2004)	—	—
Cenelec	EN 60601-1-6:2007 Medical electrical equipment — Part 1-6: General requirements for basic safety and essential performance — Collateral standard: Usability (IEC 60601-1-6:2006)	EN 60601-1-6:2004 Note 2.1	—
Cenelec	EN 60601-1-8:2004 Medical electrical equipment — Part 1-8: General requirements for safety — Collateral standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems (IEC 60601-1-8:2003)	—	—
	Amendment A1:2006 to EN 60601-1-8:2004 (IEC 60601-1-8:2003/A1:2006)	Note 3	Date expired (1.1.2007)
Cenelec	EN 60601-1-8:2007 Medical electrical equipment — Part 1-8: General requirements for basic safety and essential performance — Collateral standard: General require- ments, tests and guidance for alarm systems in medical electrical equip- ment and medical electrical systems (IEC 60601-1-8:2006)	EN 60601-1-8:2004 and its amendment	—
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)	—	—
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)	—	—
	Amendment A1:2002 to EN 60601-2-1:1998 (IEC 60601-2-1:1998/A1:2002)	Note 3	Date expired (1.6.2005)

ESO (*)	Reference and title of the standard (and reference document)	Reference of the superseded standard	Date of cessation of presumption of conformity of the superseded standard (Note 1)
Cenelec	EN 60601-2-2:2000 Medical electrical equipment — Part 2-2: Particular requirements for the safety of high frequency surgical equipment (IEC 60601-2-2:1998)	EN 60601-2-2:1993 Note 2.1	Date expired (1.8.2003)
Cenelec	EN 60601-2-2:2007 Medical electrical equipment — Part 2-2: Particular requirements for the safety of high frequency surgical equipment (IEC 60601-2-2:2006)	EN 60601-2-2:2000 Note 2.1	1.10.2009
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)	—	—
	Amendment A1:1998 to EN 60601-2-3:1993 (IEC 60601-2-3:1991/A1:1998)	Note 3	Date expired (1.7.2001)
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)	—	—
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)	—	—
Cenelec	EN 60601-2-7:1998 Medical electrical equipment — Part 2-7: Particular requirements for the safety of high-voltage generators of diagnostic X-ray generators (IEC 60601-2-7:1998)	—	—
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)	—	—
	Amendment A1:1997 to EN 60601-2-8:1997 (IEC 60601-2-8:1987/A1:1997)	Note 3	Date expired (1.6.1998)
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)	—	—
	Amendment A1:2001 to EN 60601-2-10:2000 (IEC 60601-2-10:1987/A1:2001)	Note 3	Date expired (1.11.2004)
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)	—	—
	Amendment A1:2004 to EN 60601-2-11:1997 (IEC 60601-2-11:1997/A1:2004)	Note 3	Date expired (1.9.2007)

ESO (*)	Reference and title of the standard (and reference document)	Reference of the superseded standard	Date of cessation of presumption of conformity of the superseded standard (Note 1)
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)	—	—
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)	— Note 2.3	—
	Amendment A1:2007 to EN 60601-2-13:2006 (IEC 60601-2-13:2003/A1:2006)	Note 3	1.3.2010
Cenelec	EN 60601-2-16:1998 Medical electrical equipment — Part 2-16: Particular requirements for the safety of haemodialysis, haemodiafiltration and haemofiltration equip- ment (IEC 60601-2-16:1998)	—	—
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)	EN 60601-2-17:1996 + A1:1996 Note 2.1	Date expired (1.3.2007)
Cenelec	EN 60601-2-18:1996 Medical electrical equipment — Part 2: Particular requirements for the safety of endoscopic equipment (IEC 60601-2-18:1996)	—	—
	Amendment A1:2000 to EN 60601-2-18:1996 (IEC 60601-2-18:1996/A1:2000)	Note 3	Date expired (1.8.2003)
Cenelec	EN 60601-2-19:1996 Medical electrical equipment — Part 2: Particular requirements for the safety of baby incubators (IEC 60601-2-19:1990)	—	—
	Amendment A1:1996 to EN 60601-2-19:1996 (IEC 60601-2-19:1990/A1:1996)	Note 3	Date expired (13.6.1998)
Cenelec	EN 60601-2-20:1996 Medical electrical equipment — Part 2: Particular requirements for the safety of transport incubators (IEC 60601-2-20:1990 + A1:1996)	—	—
Cenelec	EN 60601-2-21:1994 Medical electrical equipment — Part 2: Particular requirements for the safety of infant radiant warmers (IEC 60601-2-21:1994)	—	—
	Amendment A1:1996 to EN 60601-2-21:1994 (IEC 60601-2-21:1994/A1:1996)	Note 3	Date expired (13.6.1998)
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)	—	—

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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)	EN 60601-2-23:1997 Note 2.1	Date expired (1.1.2003)
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)	—	—
Cenelec	EN 60601-2-25:1995 Medical electrical equipment — Part 2-25: Particular requirements for the safety of electrocardiographs (IEC 60601-2-25:1993)	—	—
	Amendment A1:1999 to EN 60601-2-25:1995 (IEC 60601-2-25:1993/A1:1999)	Note 3	Date expired (1.5.2002)
Cenelec	EN 60601-2-26:2003 Medical electrical equipment — Part 2-26: Particular requirements for the safety of electroencephalographs (IEC 60601-2-26:2002)	EN 60601-2-26:1994 Note 2.1	Date expired (1.3.2006)
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)	EN 60601-2-27:1994 Note 2.1	Date expired (1.11.2008)
Cenelec	EN 60601-2-28:1993 Medical electrical equipment — Part 2: Particular requirements for the safety of X-ray source assemblies and X-ray tube assemblies for medical diagnosis (IEC 60601-2-28:1993)	—	—
Cenelec	EN 60601-2-29:1999 Medical electrical equipment — Part 2-29: Particular requirements for the safety of radiotherapy simulators (IEC 60601-2-29:1999)	EN 60601-2-29:1995 + A1:1996 Note 2.1	Date expired (1.4.2002)
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)	EN 60601-2-30:1995 Note 2.1	Date expired (1.2.2003)
Cenelec	EN 60601-2-31:1995 Medical electrical equipment — Part 2-31: Particular requirements for the safety of external cardiac pacemakers with internal power source (IEC 60601-2-31:1994)	—	—
	Amendment A1:1998 to EN 60601-2-31:1995 (IEC 60601-2-31:1994/A1:1998)	Note 3	Date expired (1.1.2001)
Cenelec	EN 60601-2-32:1994 Medical electrical equipment — Part 2: Particular requirements for the safety of associated equipment of X-ray equipment (IEC 60601-2-32:1994)	—	—

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Cenelec	EN 60601-2-33:2002 Medical electrical equipment — Part 2-33: Particular requirements for the safety of magnetic resonance equipment for medical diagnosis (IEC 60601-2-33:2002) + Corrigendum 11.2008	EN 60601-2-33:1995 + A11:1997 Note 2.1	Date expired (1.7.2005)
	Amendment A1:2005 to EN 60601-2-33:2002 (IEC 60601-2-33:2002/A1:2005)	Note 3	Date expired (1.11.2008)
	Amendment A2:2008 to EN 60601-2-33:2002 (IEC 60601-2-33:2002/A2:2007)	Note 3	1.2.2011
Cenelec	EN 60601-2-34:2000 Medical electrical equipment — Part 2-34: Particular requirements for the safety, including essential performance, of invasive blood pressure moni- toring equipment (IEC 60601-2-34:2000)	EN 60601-2-34:1995 Note 2.1	Date expired (1.11.2003)
Cenelec	EN 60601-2-35:1996 Medical electrical equipment — Part 2: Particular requirements for the safety of blankets, pads and mattresses, intended for heating in medical use (IEC 60601-2-35:1996)	—	—
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)	—	—
Cenelec	EN 60601-2-37:2001 Medical electrical equipment — Part 2-37: Particular requirements for the safety of ultrasonic medical diagnostic and monitoring equipment (IEC 60601-2-37:2001)	—	—
	Amendment A1:2005 to EN 60601-2-37:2001 (IEC 60601-2-37:2001/A1:2004)	Note 3	Date expired (1.1.2008)
	Amendment A2:2005 to EN 60601-2-37:2001 (IEC 60601-2-37:2001/A2:2005)	Note 3	1.12.2008
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)	EN 60601-2-37:2001 and its amendments Note 2.1	1.10.2010
Cenelec	EN 60601-2-38:1996 Medical electrical equipment — Part 2-38: Particular requirements for the safety of electrically operated hospital beds (IEC 60601-2-38:1996)	—	—
	Amendment A1:2000 to EN 60601-2-38:1996 (IEC 60601-2-38:1996/A1:1999)	Note 3	Date expired (1.1.2003)
Cenelec	EN 60601-2-39:1999 Medical electrical equipment — Part 2-39: Particular requirements for the safety of peritoneal dialysis equipment (IEC 60601-2-39:1999)	—	—

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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)	EN 60601-2-39:1999 Note 2.1	1.3.2011
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)	—	—
Cenelec	EN 60601-2-41:2000 Medical electrical equipment — Part 2-41: Particular requirements for the safety of surgical luminaires and luminaires for diagnosis (IEC 60601-2-41:2000)	—	—
Cenelec	EN 60601-2-43:2000 Medical electrical equipment — Part 2-43: Particular requirements for the safety of X-ray equipment for interventional procedures (IEC 60601-2-43:2000)	—	—
Cenelec	EN 60601-2-44:2001 Medical electrical equipment — Part 2-44: Particular requirements for the safety of X-ray equipment for computed tomography (IEC 60601-2-44:2001)	EN 60601-2-44:1999 Note 2.1	Date expired (1.7.2004)
	Amendment A1:2003 to EN 60601-2-44:2001 (IEC 60601-2-44:2001/A1:2002)	Note 3	Date expired (1.12.2005)
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)	EN 60601-2-45:1998 Note 2.1	Date expired (1.7.2004)
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)	—	—
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)	—	—
Cenelec	EN 60601-2-49:2001 Medical electrical equipment — Part 2-49: Particular requirements for the safety of multifunction patient monitoring equipment (IEC 60601-2-49:2001)	—	—
Cenelec	EN 60601-2-50:2002 Medical electrical equipment — Part 2-50: Particular requirements for the safety of infant phototherapy equipment (IEC 60601-2-50:2000)	—	—
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)	—	—

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Cenelec	EN 60627:2001 Diagnostic X-ray imaging equipment — Characteristics of general purpose and mammographic anti-scatter grids (IEC 60627:2001)	—	—
Cenelec	EN 60645-1:2001 Electroacoustics — Audiological equipment — Part 1: Pure-tone audiometers (IEC 60645-1:2001)	EN 60645-1:1994 Note 2.1	Date expired (1.10.2004)
Cenelec	EN 60645-2:1997 Audiometers — Part 2: Equipment for speech audiometry (IEC 60645-2:1993)	—	—
Cenelec	EN 60645-3:1995 Audiometers — Part 3: Auditory test signals of short duration for audiometric and neuro-otological purposes (IEC 60645-3:1994)	—	—
Cenelec	EN 60645-3:2007 Electroacoustics — Audiometric equipment — Part 3: Test signals of short duration (IEC 60645-3:2007)	EN 60645-3:1995 Note 2.1	1.6.2010
Cenelec	EN 60645-4:1995 Audiometers — Part 4: Equipment for extended high-frequency audiometry (IEC 60645-4:1994)	—	—
Cenelec	EN 61217:1996 Radiotherapy equipment — Coordinates, movements and scales (IEC 61217:1996)	—	—
	Amendment A1:2001 to EN 61217:1996 (IEC 61217:1996/A1:2000)	Note 3	Date expired (1.12.2003)
	Amendment A2:2008 to EN 61217:1996 (IEC 61217:1996/A2:2007)	Note 3	1.2.2011
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)	—	—
Cenelec	EN 62083:2001 Medical electrical equipment — Requirements for the safety of radiotherapy treatment planning systems (IEC 62083:2000)	—	—
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)	—	—
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)	—	—

ESO ⁽¹⁾	Reference and title of the standard (and reference document)	Reference of the superseded standard	Date of cessation of presumption of conformity of the superseded standard (Note 1)
Cenelec	EN 62304:2006 Medical device software — Software life-cycle processes (IEC 62304:2006)	—	—
Cenelec	EN 62366:2008 Medical devices — Application of usability engineering to medical devices (IEC 62366:2007)	—	—

⁽¹⁾ ESO: European Standardisation Organisation:

- CEN: rue de Stassart/De Stassartstraat 36, B-1050 Brussels, tel. (32-2) 550 08 11, fax (32-2) 550 08 19 (<http://www.cenorm.be>),
- Cenelec: rue de Stassart/De Stassartstraat 35, B-1050 Brussels, tel. (32-2) 519 68 71, fax (32-2) 519 69 19 (<http://www.cenelec.eu>),
- ETSI: 650, route des Lucioles, F-06921 Sophia Antipolis, tel. (33) 492 94 42 12, 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 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 requirements of the directive.

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 requirements of the directive for those products that fall within the scope of the new standard. Presumption of conformity with the essential requirements of the directive for products 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 CCCC:YYYY, its previous amendments, if any, and the new, quoted amendment. The superseded standard (column 3) therefore consists of EN CCCC: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.

Example: For EN 60601-1:1990, the following applies:

Cenelec	EN 60601-1:1990 Medical electrical equipment Part 1: General requirements for safety IEC 60601-1:1988 [The referenced standard is EN 60601-1:1990]	— [There is no superseded standard]	—
	Amendment A1:1993 to EN 60601-1:1990 IEC 60601-1:1988/A1:1991 [The referenced standard is EN 60601-1:1990 + A1:1993 to EN 60601-1:1990]	Note 3 [The superseded standard is EN 60601-1:1990]	—
	Amendment A2:1995 to EN 60601-1:1990 IEC 60601-1:1988/A2:1995 [The referenced standard is EN 60601-1:1990 + A1:1993 to EN 60601-1:1990 + A2:1995 to EN 60601-1:1990]	Note 3 [The superseded standard is EN 60601-1:1990 + A1:1993]	—
	Amendment A13:1996 to EN 60601-1:1990 [The referenced standard is EN 60601-1:1990 + A1:1993 to EN 60601-1:1990 + A2:1995 to EN 60601-1:1990 + A13:1996 to EN 60601-1:1990]	Note 3 [The superseded standard is EN 60601-1:1990 + A1:1993 + A2:1995]	Date expired (1.7.1996)