SLOVENSKI STANDARD
SIST EN 60601-1:2007/A13:2024

01-junij-2024

Medicinska električna oprema - 1. del: Splošne zahteve za varnost - Dopolnilo A13

Medical electrical equipment - Part 1: General requirements for safety

Medizinische elektrische Geräte - Teil 1: Allgemeine Festlegungen für die Sicherheit einschließlich der wesentlichen Leistungsmerkmale

Appareils électromédicaux - Partie 1: Exigences générales pour la sécurité de base et les performances essentielles

Ta slovenski standard je istoveten z: **EN 60601-1:2006/A13:2024**

ICS:

11.040.01	Medicinska oprema na splošno	Medical equipment in general

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Medical electrical equipment - Part 1: General requirements for safety

Appareils électromédicaux - Partie 1: Exigences générales pour la sécurité de base et les performances essentielles

Medizinische elektrische Geräte - Teil 1: Allgemeine Festlegungen für die Sicherheit einschließlich der wesentlichen Leistungsmerkmale

This amendment A13 modifies the European Standard EN 60601-1:2006; it was approved by CENELEC on 2024-02-28. CENELEC members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for giving this amendment the status of a national standard without any alteration.

Up-to-date lists and bibliographical references concerning such national standards may be obtained on application to the CEN-CENELEC Management Centre or to any CENELEC member.

This amendment exists in three official versions (English, French, German). A version in any other language made by translation under the responsibility of a CENELEC member into its own language and notified to the CEN-CENELEC Management Centre has the same status as the official versions.

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European Committee for Electrotechnical Standardization
Comité Européen de Normalisation Electrotechnique
Europäisches Komitee für Elektrotechnische Normung

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European foreword

This document (EN 60601-1:2006/A13:2024) has been prepared by CLC/TC 62 "Electrical Equipment in medical practice".

The following dates are fixed:

- latest date by which this document has to be implemented at national level by publication of an identical national standard or by endorsement (dop) 2025-02-28
- latest date by which the national standards conflicting with this document have to be withdrawn (dow) 2027-02-28

This amendment A13 modifies EN 60601-1:2006, and EN 60601-1:2006/A1:2013 and EN 60601-1:2006/A2:2021.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. CENELEC shall not be held responsible for identifying any or all such patent rights.

This document has been prepared under a standardization request addressed to CENELEC by the European Commission. The Standing Committee of the EFTA States subsequently approves these requests for its Member States.

For the relationship with EU Legislation, see informative Annex ZZ, which is an integral part of this document.

Any feedback and questions on this document should be directed to the users' national committee. A complete listing of these bodies can be found on the CENELEC website.

1 Replacement of Annex ZA, Annex ZZA and Annex ZZB

Replace Annex ZA, Annex ZZA and Annex ZZB with the following:

Annex ZA
(normative)

Normative references to international publications with their corresponding European publications

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

NOTE 1 Where an International Publication has been modified by common modifications, indicated by (mod), the relevant EN/HD applies.

NOTE 2 Up-to-date information on the latest versions of the European Standards listed in this annex is available here: www.cencenelec.eu.

Publication	Year	Title	EN/HD	Year
IEC 60065 (mod)	2001	Audio, video and similar electronic apparatus - Safety requirements	EN 60065	2002
			Cor. March	2006
+ A1 (mod)	2005		+ A1	2006
			Cor. August	2007
			+ A11	2008
+ A2 (mod)	2010		+ A2	2010
			+ A12	2011
IEC 60068-2-2	2007	Environmental testing Part 2-2: Tests - Test B: Dry heat	EN 60068-2-2	2007
IEC 60079-0 (mod)	-	Explosive atmospheres - Part 0: Equipment - General requirements	EN IEC 60079-0	2018
			+ AC	2020
IEC 60079-2	-	Explosive atmospheres - Part 2: Equipment protection by pressurized enclosure "p"	EN 60079-2	2014
			+ AC	2015
IEC 60079-5	-	Explosive atmospheres - Part 5: Equipment protection by powder filling "q"	EN 60079-5	2015
IEC 60079-6	-	Explosive atmospheres - Part 6: Equipment protection by liquid immersion "o"	EN 60079-6	2015
IEC/TR 60083	2015[1]	Plugs and socket-outlets for domestic and similar general use standardized in member countries of IEC	-	-
IEC 60085	-	Electrical insulation - Thermal evaluation and designation	EN 60085	2008

[1] Dated as no European equivalent exists.

IEC 60086-4	-	Primary batteries Part 4: Safety of lithium batteries	EN IEC 60086-4 + AC + AC	2019 2019 2020
IEC 60112	-	Method for the determination of the proof and the comparative tracking indices of solid insulating materials	EN IEC 60112	2020
IEC 60127-1	-	Miniature fuses Part 1: Definitions for miniature fuses and general requirements for miniature fuse-links	EN 60127-1 + A1 + A2	2006 2011 2015
IEC 60227-1	2007	Polyvinyl chloride insulated cables of rated voltages up to and including 450/750 V Part 1: General requirements	EN 50525-1 [2]	2011
IEC 60245-1 + A1	2003 2007	Rubber insulated cables - Rated voltages up to and including 450/750 V Part 1: General requirements	EN 50525-1 [2]	2011
IEC 60252-1	-	+ AC motor capacitors Part 1: General - Performance, testing and rating - Safety requirements - Guidance for installation and operation	EN 60252-1 + A1	2011 2013
IEC 60320-1	-	Appliance couplers for household and similar general purposes Part 1: General requirements	EN IEC 60320-1	2021
IEC 60335-1 (mod)	2010	Household and similar electrical appliances - Safety Part 1: General requirements	EN 60335-1 + AC + A11 + A12	2012 2014 2014 2017
IEC 60364-4-41 (mod)	-	Low-voltage electrical installations Part 4-41: Protection for safety - Protection against electric shock	HD 60364-4-41 + A11 + A12	2017 2017 2019
IEC 60384-14	2005	Fixed capacitors for use in electronic equipment Part 14: Sectional specification - Fixed capacitors for electromagnetic interference suppression and connection to the supply mains	EN 60384-14	2005
IEC 60417	Data base	Graphical symbols for use on equipment available from http://www.graphical-symbols.info/equipment	-	-
IEC 60445	-	Basic and safety principles for man-machine interface, marking and identification - Identification of equipment terminals, conductor terminations and conductors	EN IEC 60445	2021
IEC 60447	-	Basic and safety principles for man-machine interface, marking and identification - Actuating principles	EN 60447	2004

[2] EN 50525-1:2011, *Electric cables - Low voltage energy cables of rated voltages up to and including 450/750 V (U0/U) - Part 1: General requirements*, which is related to, but not directly equivalent with, IEC 60227-1 and IEC 60245-1, applies instead.

IEC 60447	-	Basic and safety principles for man-machine interface, marking and identification - Actuating principles	EN 60447	2004
IEC 60529 + A1	1989 1999	Degrees of protection provided by enclosures (IP Code)	EN 60529 Cor. May + A1	1991 1993 2000
IEC 60601-1-2 + A1	2014 2020	Medical electrical equipment Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic disturbances- Requirements and tests	EN 60601-1-2 + A1	2015 2021
IEC 60601-1-3 + A1	2008 2013	Medical electrical equipment - Part 1-3: General requirements for basic safety and essential performance - Collateral Standard: Radiation protection in diagnostic X-ray equipment	EN 60601-1-3 Cor. March + A1 + AC + A11	2008 2010 2013 2014 2016
IEC 60601-1-3 + A1	2008 2013	Medical electrical equipment - Part 1-3: General requirements for basic safety and essential performance - Collateral Standard: Radiation protection in diagnostic X-ray equipment	EN 60601-1-3 Cor. March + A1 + AC + A11	2008 2010 2013 2014 2016
IEC 60601-1-6 + A1 + A2	2010 2013 2020	Medical electrical equipment Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability	EN 60601-1-6 + A1 + A2	2010 2015 2021
IEC 60601-1-8 + A1 + A2	2006 2012 2020	Medical electrical equipment Part 1-8: General requirements for basic safety and essential performance - Collateral Standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems	EN 60601-1-8 Cor. March + A1 + AC + A11 + A2	2007 2010 2013 2014 2017 2021
IEC 60664-1	2007	Insulation coordination for equipment within low-voltage systems Part 1: Principles, requirements and tests	EN 60664-1	2007
IEC 60695-11-10	-	Fire hazard testing - Part 11-10: Test flames - 50 W horizontal and vertical flame test methods	EN 60695-11-10 + AC	2013 2014
IEC 60730-1 (mod)	2010	Automatic electrical controls for household and similar use Part 1: General requirements	EN 60730-1	2011
IEC 60747-5-5	2007	Semiconductor devices - Discrete devices - Part 5-5: Optoelectronic devices - Photocouplers	EN 60747-5-5	2011
IEC 60825-1	2014	Safety of laser products - Part 1: Equipment classification and requirements	EN 60825-1 + AC + A11 + AC	2014 2017 2021 2022
IEC 60851-3	2009	Winding wires - Test methods - Part 3: Mechanical properties	EN 60851-3	2009

IEC 60851-5	2008	Winding wires - Test methods - Part 5: Electrical properties	EN 60851-5	2008
IEC 60851-6	1996	Winding wires - Test methods - Part 6: Thermal properties	EN 60851-6	1996
+ A1	1997		+ A1	1997
IEC 60851-6	1996	Winding wires - Test methods Part 6: Thermal properties	EN 60851-6	1996
+ A1	1997		+ A1	1997
IEC 60884-1	-	Plugs and socket-outlets for household and similar purposes - Part 1: General requirements	IEC 60884-1	2022
IEC 60950-1	2005	Information technology equipment - Safety - Part 1: General requirements	EN 60950-1	2006
(mod)			+ A11	2009
+ A1	2009		+ A1	2010
	2013		+ A12	2011
			+ AC	2011
+ A2			+ A2	2013
IEC 61058-1	2000	Switches for appliances - Part 1: General requirements	EN 61058-1	2002
(mod)			+ A2	2008
+ A1	2001			
+ A2	2007			
IEC 61558-2-1	-	Safety of power transformers, power supplies, reactors and similar products - Part 2-1: Particular requirements and tests for separating transformers and power supplies incorporating separating transformers for general applications	EN 61558-2-1	2007
IEC 61672-1	-	Electroacoustics - Sound level meters Part 1: Specifications	EN 61672-1	2013
IEC 61672-2	-	Electroacoustics - Sound level meters Part 2: Pattern evaluation tests	EN 61672-2	2013
			+ A1	2017
IEC 61965	-	Mechanical safety of cathode ray tubes	EN 61965	2003
IEC 62133	-	Secondary cells and batteries containing alkaline or other non-acid electrolytes – Safety requirements for portable sealed secondary cells, and for batteries made from them, for use in portable applications	EN 62133	2013
IEC 62133-2	-	Secondary cells and batteries containing alkaline or other non-acid electrolytes - Safety requirements for portable sealed secondary cells, and for batteries made from them, for use in portable applications - Part 2: Lithium systems	EN 62133-2	2017
			+ A1	2021
			+ AC	2022
IEC 62304	2006	Medical device software – Software lifecycle processes	EN 62304	2006
			Cor. Nov.	2008
+ A1	2015		+ A1	2015
IEC 62368-1	2018	Audio/video, information and communication technology equipment - Part 1: Safety requirements	EN IEC 62368-1	2020
			+ A11	2020
			+ AC	2020

ISO 780	-	Packaging - Distribution packaging - Graphical symbols for handling and storage of packages	EN ISO 780	2015
ISO 1853	2018[3]	Conducting and dissipative rubbers, vulcanized or thermoplastic - Measurement of resistivity	-	-
ISO 2878	2017[4]	Rubber, vulcanized - Antistatic and conductive products - Determination of electrical resistance	-	-
ISO 2882	1979[5]	Rubber, vulcanized - Antistatic and conductive products for hospital use - Electrical resistance limits	-	-
ISO 3746	-	Acoustics - Determination of sound power levels of noise sources using sound pressure - Survey method using an enveloping measurement surface over a reflecting plane	EN ISO 3746	2010
ISO 3864-1	2011	Graphical symbols - Safety colours and safety signs - Part 1: Design principles for safety signs in workplaces and public areas	-	-
ISO 5349-1	-	Mechanical vibration - Measurement and evaluation of human exposure to hand-transmitted vibration - Part 1: General requirements	EN ISO 5349-1	2001
ISO 7000	2004	Graphical symbols for use on equipment – Collection of symbols	-	-
ISO 7010	2019	Graphical symbols – Safety colours and safety signs – Registered safety signs	EN ISO 7010	2012
			+ A1	2014
			+ A2	2014
			+ A3	2014
			+ A4	2014
			+ A5	2015
			+ A6	2016
			+ A7	2017
ISO 9614-1	-	Acoustics – Determination of sound power levels of noise sources using sound intensity – Measurement at discrete points	EN ISO 9614-1	2009
ISO 10993	series	Biological evaluation of medical devices		
		Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process	EN ISO 10993-1	2020
		Biological evaluation of medical devices - Part 2: Animal welfare requirements	EN ISO 10993-2	2006
		Biological evaluation of medical devices - Part 3: Tests for genotoxicity, carcinogenicity and reproductive toxicity	EN ISO 10993-3	2014
		Biological evaluation of medical devices - Part 4: Selection of tests for interactions with blood	EN ISO 10993-4	2017

[3] Dated as no European equivalent exists.
[4] Dated as no European equivalent exists.
[5] Dated as no European equivalent exists.

		Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity	EN ISO 10993-5	2009
		Biological evaluation of medical devices - Part 6: Tests for local effects after implantation	EN ISO 10993-6	2016
		Biological evaluation of medical devices - Part 7: Ethylene oxide sterilization residuals	EN ISO 10993-7 + AC + A1	2008 2009 2020
		Biological evaluation of medical devices - Part 9: Framework for identification and quantification of potential degradation products	EN ISO 10993-9	2009
		Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization	EN ISO 10993-10	2013
		Biological evaluation of medical devices - Part 11: Tests for systemic toxicity	EN ISO 10993-11	2018
		Biological evaluation of medical devices - Part 12: Sample preparation and reference materials	EN ISO 10993-12	2012
		Biological evaluation of medical devices - Part 13: Identification and quantification of degradation products from polymeric medical devices	EN ISO 10993-13	2010
		Biological evaluation of medical devices - Part 14: Identification and quantification of degradation products from ceramics	EN ISO 10993-14	2009
		Biological evaluation of medical devices - Part 15: Identification and quantification of degradation products from metals and alloys	EN ISO 10993-15	2020
		Biological evaluation of medical devices - Part 16: Toxicokinetic study design for degradation products and leachables	EN ISO 10993-16	2017
		Biological evaluation of medical devices - Part 17: Establishment of allowable limits for leachable substances	EN ISO 10993-17	2009
		Biological evaluation of medical devices - Part 18: Chemical characterization of materials	EN ISO 10993-18	2020
		Biological evaluation of medical devices - Part 19: Physico-chemical, morphological and topographical characterization of materials	ISO/TS 10993-19	2006
		Biological evaluation of medical devices - Part 20: Principles and methods for immunotoxicology testing of medical devices	ISO/TS 10993-20	2006
ISO 18562-1	2017	Biocompatibility evaluation of breathing gas pathways in healthcare applications -- Part 1: Evaluation and testing within a risk management process	EN ISO 18562-1	2020
ISO 18562-2	2017	Biocompatibility evaluation of breathing gas pathways in healthcare applications -- Part 2: Tests for emissions of particulate matter	EN ISO 18562-2	2020
ISO 18562-3	2017	Biocompatibility evaluation of breathing gas pathways in healthcare applications -- Part 3: Tests for emissions of volatile organic	EN ISO 18562-3	2020

		compounds (VOCs)		
ISO 18562-4	2017	Biocompatibility evaluation of breathing gas pathways in healthcare applications -- Part 4: Tests for leachables in condensate	EN ISO 18562-4	2020
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	EN ISO 11135-1	2007
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	EN ISO 11137-1	2006
ISO 13857	2008	Safety of machinery – Safety distances to prevent hazard zones being reached by the upper and lower limbs	EN ISO 13857	2008
ISO 14971	2019	Medical devices – Application of risk management to medical devices	EN ISO 14971	2019
ISO 15223-1	2016	ISO 15223-1:2012, Medical devices – Symbols to be used with medical device labels, labelling and information to be supplied – Part 1: General requirements	EN ISO 15223-1	2016
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	EN ISO 17665-1	2006
ISO 23529	2016[6]	Rubber – General procedures for preparing and conditioning test pieces for physical test methods	-	-
ISO 80000-1	2009	Quantities and units – Part 1: General	EN ISO 80000-1	2013

[6] Dated as no European equivalent exists.

Annex ZZ
(informative)

Relationship between this European standard and the General Safety and Performance Requirements of Regulation (EU) 2017/745 aimed to be covered

This European standard has been prepared under M/575 to provide one voluntary means of conforming to the General Safety and Performance Requirements of Regulation (EU) 2017/745 of 5 April 2017 concerning medical devices [OJ L 117] and to system or process requirements including those relating to quality management systems, risk management, post-market surveillance systems, clinical investigations, clinical evaluation or post-market clinical follow-up.

Once this standard is cited in the Official Journal of the European Union under that Regulation, compliance with the normative clauses of this standard given in Table ZZ.1 confers, within the limits of the scope of this standard, a presumption of conformity with the corresponding General Safety and Performance Requirements of that Regulation, and associated EFTA regulations.

Where a definition in this standard differs from a definition of the same term set out in Regulation (EU) 2017/745, the differences shall be indicated in this Annex Z. For the purpose of using this standard in support of the requirements set out in Regulation (EU) 2017/745, the definitions set out in this Regulation prevail.

Where the European standard is an adoption of an International Standard, the scope of this standard can differ from the scope of the European Regulation that it supports. As the scope of the applicable regulatory requirements differ from nation to nation and region to region, the standard can only support European regulatory requirements to the extent of the scope of the European regulation for medical devices (EU) 2017/745.

For application of this European standard under Regulation (EU) 2017/745, its scope is limited to medical devices for use with human patients. This affects all clauses of this European standard.

NOTE 1 Where a reference from a clause of this standard to the risk management process is made, the risk management process needs to be in compliance with Regulation (EU) 2017/745. This means that risks have to be ‘reduced as far as possible’, ‘reduced to the lowest possible level’, ‘reduced as far as possible and appropriate’, ‘removed or reduced as far as possible’, ‘eliminated or reduced as far as possible’, ’removed or minimized as far as possible’, or ‘minimized’, according to the wording of the corresponding General Safety and Performance Requirement.

NOTE 2 The manufacturer’s policy for determining **acceptable risk** must be in compliance with General Safety and Performance Requirements 1, 2, 3, 4, 5, 8, 9, 10, 11, 14, 16, 17, 18, 19, 20, 21 and 22 of the Regulation.

NOTE 3 When a General Safety and Performance Requirement does not appear in Table ZZ.1, it means that it is not addressed by this European Standard.