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BRITISH STANDARD

BS EN 60601-1:2006 +A12:2014
Incorporating corrigenda December 2006, December 2007, March 2010 and July 2014

Medical electrical equipment —

Part 1: General requirements for basic safety and essential performance

ICS 11.040.01

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BSI British Standards

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National foreword

This British Standard is the UK implementation of EN 60601-1:2006+A12:2014. It is identical to IEC 60601-1:2005, incorporating amendment A1:2013 and corrigendum July 2014. It supersedes BS EN 60601-1:2006 +A1:2013, which will be withdrawn on 26 March 2015.

The start and finish of text introduced or altered by corrigendum is indicated in the text by tags. Text altered by IEC corrigendum December 2006 is indicated in the text by ⟦AC1⟩ ⟨AC1⟧. Text altered by IEC corrigendum December 2007 is indicated in the text by ⟦AC2⟩ ⟨AC2⟧. Text altered by IEC corrigendum July 2014 is indicated in the text by ⟦AC3⟩ ⟨AC3⟧.

The start and finish of text introduced or altered by amendment is indicated in the text by tags. Tags indicating changes to IEC text carry the number of the IEC amendment. For example, text altered by IEC amendment 1 is indicated by ⟦A1⟩ ⟨A1⟧.

The UK participation in its preparation was entrusted by Technical Committee CH/62, Electrical Equipment in Medical Practice, to Subcommittee CH/62/1, Common aspects of Electrical Equipment used in Medical Practice.

A list of organizations represented on this subcommittee can be obtained on request to its secretary.

The publication does not purport to include all the necessary provisions of a contract. Users are responsible for its correct application.

Compliance with a British Standard cannot confer immunity from legal obligations.

This British Standard was published under the authority of the Standards Policy and Strategy Committee on 30 November 2006

Amendments/corrigenda issued since publication

Date	Comments
31 May 2011	Implementation of IEC corrigenda December 2006 and December 2007 (tagged) and implementation of CENELEC corrigendum March 2010: modification of CENELEC Foreword and Annexes ZA and ZZ
29 February 2012	Implementation of CENELEC amendment A11:2011: Annex ZZ replaced by Annexes ZZA and ZZB
31 December 2012	Implementation of IEC amendment 1:2013 with CENELEC endorsement A1:2013. Annex ZA replaced and Annex ZZ added
30 November 2014	Implementation of IEC corrigendum July 2014: Figure 12 updated
30 November 2014	Implementation of CENELEC amendment A12:2014: Annex ZZ updated to Annex ZZA, previous Annex ZZA deleted. Annez ZZB inserted

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EUROPEAN STANDARD **EN 60601-1:2006+A12**

NORME EUROPÉENNE

EUROPÄISCHE NORM October 2014

ICS 11.040

English version

Medical electrical equipment
Part 1: General requirements for basic safety and essential performance
(IEC 60601-1:2005)

Appareils électromédicaux
Partie 1: Exigences générales
pour la sécurité de base
et les performances essentielles
(CEI 60601-1:2005)

Medizinische elektrische Geräte
Teil 1: Allgemeine Festlegungen
für die Sicherheit einschließlich
der wesentlichen Leistungsmerkmale
(IEC 60601-1:2005)

This European Standard was approved by CENELEC on 2006-09-12. CENELEC members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for giving this European Standard 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 Central Secretariat or to any CENELEC member.

This European Standard 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 Central Secretariat has the same status as the official versions.

CENELEC members are the national electrotechnical committees of Austria, Belgium, Cyprus, the Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, the Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland and the United Kingdom.

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

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Ref. No. EN 60601-1:2006 E

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Foreword

The text of document 62A/505A//FDIS, future edition 3 of IEC 60601-1, prepared by SC 62A, Common aspects of electrical equipment used in medical practice, of IEC TC 62, Electrical equipment in medical practice, was submitted to the IEC-CENELEC parallel vote and was approved by CENELEC as EN 60601-1 on 2006-09-12.

The following date was fixed:

– latest date by which the EN has to be implemented at national level by publication of an identical national standard or by endorsement	(dop)	2007-07-01
– latest date by which the national standards conflicting with the EN have to be withdrawn.	(dow)	2012-06-01

This European Standard supersedes EN 60601-1:1990 and its amendments.

This EN 60601-1:2006 has been significantly restructured compared to EN 60601-1:1990. Requirements in the electrical section have been further aligned with those for information technology equipment covered by EN 60950-1 and a requirement for including a RISK MANAGEMENT PROCESS has been added. For an expanded description of this revision, see Clause A.3.

This European Standard has been prepared under a mandate given to CENELEC by the European Commission and the European Free Trade Association and covers essential requirements of EC Directives 90/385/EEC and 93/42/EEC. See Annex ZZ.

In this standard the following print types are used:

- requirements and definitions: in roman type;
- *test specifications: in italic type*;
- informative material appearing outside of tables, such as notes, examples and references: in smaller type. Normative text of tables is also in a smaller type;
- TERMS USED THROUGHOUT THIS STANDARD THAT HAVE BEEN DEFINED IN CLAUSE 3 AND ALSO GIVEN IN THE INDEX: IN SMALL CAPITALS.

In referring to the structure of this standard, the term

– “clause” means one of the seventeen numbered divisions within the table of contents, inclusive of all subdivisions (e.g. Clause 7 includes subclauses 7.1, 7.2, etc.);

– “subclause” means a numbered subdivision of a clause (e.g. 7.1, 7.2 and 7.2.1 are all subclauses of Clause 7).

References to clauses within this standard are preceded by the term “Clause” followed by the clause number. References to subclauses within this standard are by number only. In this standard, the conjunctive “or” is used as an “inclusive or” so a statement is true if any combination of the conditions is true.

The verbal forms used in this standard conform to usage described in Annex G of the ISO/IEC Directives, Part 2. For the purposes of this standard, the auxiliary verb:

- “shall” means that compliance with a requirement or a test is mandatory for compliance with this standard;
- “should” means that compliance with a requirement or a test is recommended but is not mandatory for compliance with this standard;
- “may” is used to describe a permissible way to achieve compliance with a requirement or test.

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An asterisk (*) as the first character of a title or at the beginning of a paragraph or table title indicates that there is guidance or rationale related to that item in Annex A.

Annexes ZA and ZZ have been added by CENELEC.

Endorsement notice

The text of the International Standard IEC 60601-1:2005 was approved by CENELEC as a European Standard without any modification.

The contents of the corrigendum of March 2010 have been included in this copy.

Foreword to amendment A11

This document (EN 60601-1:2006/A11:2011) 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)	2012-10-01
• latest date by which the national standards conflicting with this document have to be withdrawn	(dow)	2014-10-01

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

Foreword to amendment A1

The text of document 62A/805/FDIS, future IEC 60601-1:2005/A1, prepared by SC 62A, "Common aspects of electrical equipment used in medical practice", of IEC TC 62, "Electrical equipment in medical practice" was submitted to the IEC-CENELEC parallel vote and approved by CENELEC as EN 60601-1:2006/A1:2013.

The following dates are fixed:

• latest date by which the document has to be implemented at national level by publication of an identical national standard or by endorsement	(dop)	2014-06-24
• latest date by which the national standards conflicting with the document have to be withdrawn	(dow)	2018-12-24

In the foreword of EN 60601-1:2006, ***replace*** *the first sentence of the third paragraph by:*

This European Standard supersedes EN 60601-1:1990 and its amendments, EN 60601-1-1:2001 and EN 60601-1-4:1996 + A1:1999.

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

This document has been prepared under a mandate given to CENELEC by the European Commission and the European Free Trade Association, and supports essential requirements of EU Directive(s).

For the relationship with EU Directive(s) see informative Annex ZZ, which is an integral part of this document.

Endorsement notice

The text of the International Standard IEC 60601-1:2005/A1:2012 was approved by CENELEC as a European Standard without any modification.

***Replace** the Bibliography of EN 60601-1:2006 by:*

IEC 60073	NOTE	Harmonized as EN 60073.
IEC 60086-1	NOTE	Harmonized as EN 60086-1.
IEC 60127-6	NOTE	Harmonized as EN 60127-6.
IEC 60309-1	NOTE	Harmonized as EN 60309-1.
IEC 60332-1-2	NOTE	Harmonized as EN 60332-1-2.
IEC 60332-2-2	NOTE	Harmonized as EN 60332-2-2.
IEC 60317-43	NOTE	Harmonized as EN 60317-43.
IEC 60601-1-1:2000	NOTE	Harmonized as EN 60601-1-1:2001 (not modified).
IEC 60601-1-4:1996	NOTE	Harmonized as EN 60601-1-4:1996 + A1:1999 (not modified).
IEC 60601-1-11	NOTE	Harmonized as EN 60601-1-11.
IEC 60601-2-22	NOTE	Harmonized as EN 60601-2-22.
IEC 60601-2-49:2001	NOTE	Harmonized as EN 60601-2-49:2001 (not modified).
IEC 60695-1-10	NOTE	Harmonized as EN 60695-1-10.
IEC 60721 series	NOTE	Harmonized in EN 60721 series.
IEC 60990	NOTE	Harmonized as EN 60990.
IEC 61000-4-11	NOTE	Harmonized as EN 61000-4-11.
IEC 61010 series	NOTE	Harmonized in EN 61010 series.
IEC 61010-1:2010	NOTE	Harmonized as EN 61010-1:2010 (not modified).
IEC 61140:2001	NOTE	Harmonized as EN 61140:2002 (not modified).
IEC 61558-1	NOTE	Harmonized as EN 61558-1.
IEC 61558-2-4	NOTE	Harmonized as EN 61558-2-4.
IEC 61558-2-23	NOTE	Harmonized as EN 61558-2-23.
IEC 62079:2001	NOTE	Harmonized as EN 62079:2001 (not modified).
IEC 62353	NOTE	Harmonized as EN 62353.
IEC 62471:2006	NOTE	Harmonized as EN 62471:2008 (modified).
IEC 80001-1:2010	NOTE	Harmonized as EN 80001-1:2011 (not modified).

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ISO 407	NOTE	Harmonized as EN ISO 407.
ISO 7396-1	NOTE	Harmonized as EN ISO 7396-1.
ISO 8041	NOTE	Harmonized as EN ISO 8041.
ISO 13485	NOTE	Harmonized as EN ISO 13485.
ISO 15001	NOTE	Harmonized as EN ISO 15001.

Foreword to amendment A12

This document (EN 60601-1:2006/A12:2014) has been prepared by CLC/TC 62 “Electrical equipment in medical practice”.

The following dates are fixed:

- latest date by which the document has to be implemented at national level by publication of an identical national standard or by endorsement (dop) 2015-03-26
- latest date by which the national standards conflicting with the document have to be withdrawn (dow) 2015-03-26

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

This document has been prepared under a mandate given to CENELEC by the European Commission and the European Free Trade Association, and supports essential requirements of EU Directive(s).

For the relationship with EU Directive(s) see informative Annexes ZZA and ZZB, which are an integral part of this document.

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Annex ZA
(normative)

Normative references to international publications with their corresponding European publications

The following documents, in whole or in part, are normatively referenced in this document and are indispensable for its application. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

NOTE When an international publication has been modified by common modifications, indicated by (mod), the relevant EN/HD applies.

Publication	Year	Title	EN/HD and IEC/ISO	Year
IEC 60065 (mod)	2001	Audio, video and similar electronic apparatus - Safety requirements	EN 60065 + corr. March	2002
A1 (mod)	2005		A1 + corr. August A11	2006 2007 2008
A2 (mod	2010		A2 A12	2010 2012
IEC 60068-2-2	2007	Environmental testing Part 2: Tests - Test B: Dry heat	EN 60068-2-2	2007
IEC 60079-0 (mod)	- [1)]	Explosive atmospheres - Part 0: Equipment - General requirements	EN 60079-0	2012
IEC 60079-2	- [1)]	Explosive atmospheres - Part 2: Equipment protection by pressurized enclosure "p"	EN 60079-2	2007
IEC 60079-5	- [1)]	Explosive atmospheres - Part 5: Equipment protection by powder filling "q"	EN 60079-5	2007
IEC 60079-6	- [1)]	Explosive atmospheres - Part 6: Equipment protection by oil immersion "o"	EN 60079-6	2007
IEC 60083	- [1)]	Plugs and socket-outlets for domestic and similar general use standardized in member countries of IEC	IEC 60083	2009
IEC 60085	- [1)]	Electrical insulation - Thermal evaluation and designation	EN 60085	2008
IEC 60086-4	- [1)]	Primary batteries Part 4: Safety of lithium batteries	EN 60086-4	2007
IEC 60112	- [1)]	Method for the determination of the proof and the comparative tracking indices of solid insulating materials	EN 60112	2003
IEC 60127-1	2006	Miniature fuses Part 1: Definitions for miniature fuses and general requirements for miniature fuse-links	EN 60127-1	2006

[1)] Undated reference, converted to dated reference in this European Standard.

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Publication	Year	Title	EN/HD and IEC/ISO	Year
IEC 60227-1 [2]	1993	Polyvinyl chloride insulated cables of rated voltages up to and including 450/750 V Part 1: General requirements		
A1	1995			
A2	1998		HD 21.1 S4	2002
IEC 60245-1 [3]	2003	Rubber insulated cables - Rated voltages up to and including 450/750 V Part 1: General requirements	IEC 60245-1	2003
IEC 60252-1	- [1]	AC motor capacitors Part 1: General - Performance, testing and rating - Safety requirements - Guidance for installation and operation	EN 60252-1	2011
IEC 60320-1	- [1]	Appliance couplers for household and similar general purposes Part 1: General requirements	EN 60320-1	2001
IEC 60335-1 (mod)	2010	Household and similar electrical appliances - Safety Part 1: General requirements	EN 60335-1	2012
IEC 60364-4-41 (mod)	2005	Low-voltage electrical installations Part 4-41: Protection for safety - Protection against electric shock	HD 60364-4-41	2006
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 60417	2004
IEC 60445	- [1]	Basic and safety principles for man-machine interface, marking and identification - Identification of equipment terminals, conductor terminations and conductors	EN 60445	2010
IEC 60447	- [1]	Basic and safety principles for man-machine interface, marking and identification - Actuating principles	EN 60447	2004
IEC 60529	1989	Degrees of protection provided by enclosures (IP Code)	EN 60529 + corr. May	1991 1993
A1	1999		A1	2000
IEC 60601-1-2	- [1]	Medical electrical equipment Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests	EN 60601-1-2	2007
IEC 60601-1-3	- [1]	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 + corr. March	2008 2010
A1	- [1]		A1	2013

[2] HD 21.1 S4:2002, *Cables of rated voltages up to and including 450/750 V and having thermoplastic insulation - Part 1: General requirements,* which is related to, but not directly equivalent with, IEC 60227-1, applies instead.

[3] HD 22.1 S4:2002, *Cables of rated voltages up to and including 450/750 V and having cross-linked insulation - Part 1: General requirements*, which is related to, but not directly equivalent with, IEC 60245-1, applies instead.

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Publication	Year	Title	EN/HD and IEC/ISO	Year
IEC 60601-1-6	-[1)]	Medical electrical equipment Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability	EN 60601-1-6	2010
IEC 60601-1-8	-[1)]	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 + corr. March	2007 2010
A1	-[1)]		A1	2013
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	-[1)]	Fire hazard testing Part 11-10: Test flames - 50 W horizontal and vertical flame test methods	EN 60695-11-10	1999
A1				2003
IEC 60730-1 (mod)	2010	Automatic electrical controls for household and similar use Part 1: General requirements	EN 60730-1	2011
IEC 60825-1	2007	Safety of laser products Part 1: Equipment classification and requirements	EN 60825-1	2007
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 A1	1996 1997	Winding wires - Test methods Part 6: Thermal properties	EN 60851-6 A1	1996 1997
IEC/TR 60878	2003	Graphical symbols for electrical equipment in medical practice	IEC/TR 60878	2003
IEC 60884-1	-[1)]	Plugs and socket-outlets for household and similar purposes Part 1: General requirements	IEC 60884-1	2013
IEC 60950-1 (mod)	2001	Information technology equipment - Safety Part 1: General requirements	EN 60950-1 + corr. April A11	2001 2004 2004
IEC 61058-1 (mod) A1 A2	2000 2001 2007	Switches for appliances Part 1: General requirements	EN 61058-1 A2	2002 2008
IEC 61558-2-1	-[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	-[1)]	Electroacoustics - Sound level meters Part 1: Specifications	EN 61672-1	2003
IEC 61672-2	-[1)]	Electroacoustics - Sound level meters Part 2: Pattern evaluation tests	EN 61672-2	2003

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Publication	Year	Title	EN/HD and IEC/ISO	Year
IEC 61965	- [1)]	Mechanical safety of cathode ray tubes	EN 61965	2003
IEC 62133	- [1)]	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 62304	2006	Medical device software – Software lifecycle processes	EN 62304 + corr. November	2006 2008
ISO 780	- [1)]	Packaging - Pictorial marking for handling of goods	EN ISO 780	1999
ISO 1853	- [1)]	Conducting and dissipative rubbers, vulcanized or thermoplastic - Measurement of resistivity	ISO 1853	2011
ISO 2878	- [1)]	Rubber, vulcanized - Antistatic and conductive products - Determination of electrical resistance	ISO 2878	2011
ISO 2882	- [1)]	Rubber, vulcanized - Antistatic and conductive products for hospital use - Electrical resistance limits	ISO 2882	1997
ISO 3746	- [1)]	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	2002	Graphical symbols - Safety colours and safety signs Part 1: Design principles for safety signs in workplaces and public areas	ISO 3864-1	2011
ISO 7000	2004	Graphical symbols for use on equipment – Collection of symbols	ISO 7000	2004
ISO 7010	2011	Graphical symbols – Safety colours and safety signs – Registered safety signs	EN ISO 7010	2012
ISO 9614-1	- [1)]	Acoustics – Determination of sound power levels of noise sources using sound intensity – Measurement at discrete points	EN ISO 9614-1	2009
ISO 10993 all parts	- [1)]	Biological evaluation of medical devices	See list below	
ISO 10993-1	2009	Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process	EN ISO 10993-1	2009
+ corr June	2010			
ISO 10993-2	2006	Biological evaluation of medical devices - Part 2: Animal welfare requirements	EN ISO 10993-2	2006
ISO 10993-3	2003	Biological evaluation of medical devices - Part 3: Tests for genotoxicity, carcinogenicity and reproductive toxicity	EN ISO 10993-3	2003
ISO 10994-4	2002	Biological evaluation of medical devices - Part 4: Selection of tests for interactions with blood		
A1	2006		EN ISO 10993-4	2009
ISO 10993-5	2009	Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity	EN ISO 10993-5	2009
ISO 10993-6	2007	Biological evaluation of medical devices - Part 6: Tests for local effects after implantation	EN ISO 10993-6	2009

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Publication	Year	Title	EN/HD and IEC/ISO	Year
ISO 10993-7	2008	Biological evaluation of medical devices - Part 7: Ethylene oxide sterilization residuals	EN ISO 10993-7	2008
+ corr November	2009		+ AC	2009
ISO 10993-9	2009	Biological evaluation of medical devices - Part 9: Framework for identification and quantification of potential degradation products	EN ISO 10993-9	2009
ISO 10993-10	2010	Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization	EN ISO 10993-10	2010
ISO 10993-11	2006	Biological evaluation of medical devices - Part 11: Tests for systemic toxicity	EN ISO 10993-11	2009
ISO 10993-12	2012	Biological evaluation of medical devices - Part 12: Sample preparation and reference materials	EN ISO 10993-12	2012
ISO 10993-13	2010	Biological evaluation of medical devices - Part 13: Identification and quantification of degradation products from polymeric medical devices	EN ISO 10993-13	2010
ISO 10993-14	2001	Biological evaluation of medical devices - Part 14: Identification and quantification of degradation products from ceramics	EN ISO 10993-14	2009
ISO 10993-15	2000	Biological evaluation of medical devices - Part 15: Identification and quantification of degradation products from metals and alloys	EN ISO 10993-15	2009
ISO 10993-16	2010	Biological evaluation of medical devices - Part 16: Toxicokinetic study design for degradation products and leachables	EN ISO 10993-16	2010
ISO 10993-17	2002	Biological evaluation of medical devices - Part 17: Establishment of allowable limits for leachable substances	EN ISO 10993-17	2009
ISO 10993-18	2005	Biological evaluation of medical devices - Part 18: Chemical characterization of materials	EN ISO 10993-18	2009
ISO/TS 10993-19	2006	Biological evaluation of medical devices - Part 19: Physico-chemical, morphological and topographical characterization of materials	ISO/TS 10993-19	2006
ISO/TS 10993-20	2006	Biological evaluation of medical devices - Part 20: Principles and methods for immunotoxicology testing of medical devices	ISO/TS 10993-20	2006
ISO 11135-1	2007	Sterilization of health care products – Ethylene oxide – Part 1:Requirements for development, validation and routine control of a sterilization process formedical 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	2007	Medical devices – Application of risk management to medical devices	EN ISO 14971	2012
ISO 15223-1	2012	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	2012

Publication	Year	Title	EN/HD and IEC/ISO	Year
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	- [1)]	Rubber – General procedures for preparing and conditioning test pieces for physical test methods	ISO 23529	2010
ISO 80000-1	2009	Quantities and units – Part 1: General	EN ISO 80000-1	2013

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Annex ZZA
(informative)

Relationship between this European Standard and the Essential Requirements of EU Directive 93/42/EEC on Medical Devices

This European Standard has been prepared under a mandate given to CENELEC by the European Commission and the European Free Trade Association to provide a means of conforming to the Essential Requirements given in Annex I of the EC Directives 93/42/EEC as amended by 2007/47/EC.

General Guidance:

Once this standard will be cited in the Official Journal of the European Union under that Directive, compliance with the clauses of this standard given in Table ZZA.1 confers, within the limits of the scope of this standard, a presumption of conformity with the corresponding Essential Requirements (ERs) of that Directive and associated EFTA regulations.

NOTE 1 This standard is intended to be applied in its entirety only. Selected clauses or subclauses may be not applicable due to the specific type of equipment under consideration. It is necessary to understand and apply Clauses 1 to 5. It is also recommended to understand and apply those clauses which contain general requirements related to a specific subclause. Elements of the standard that are not cited in Table ZZA.1 may be relevant for the appropriate fulfilment of certain essential requirements through indirect reference, and for safety and performance aspects of the device, that are not addressed through essential requirements.

NOTE 2 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 to the MDD (Directive 93/42/EEC amended by 2007/47/EC). This means that risks have to be reduced "as far as possible", "to a minimum", "to the lowest possible level", "minimized" or "removed", according to the wording of the corresponding essential requirement.

NOTE 3 With respect to note 4 of clause 4.2.2 General requirement for risk management, the manufacturer's policy for determining **acceptable risk** must be in compliance with essential requirements 1, 2, 5, 6, 7, 8, 9, 11 and 12 of the directive.

NOTE 4 References in the clauses 3 to 17 or in the Annexes of this standard specify whether the normative references listed in Clause 2 as cited in Annex ZA are to be applied in whole or in part.

NOTE 5 This Annex ZZA is based on Normative References according to Annex ZA, replacing the references in the core text.

WARNING: Other requirements and other EU Directives and Regulations may be applicable to the product(s) falling within the scope of this standard.

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Table ZZA.1: Relationship between Essential Requirements of Directive 93/42/EEC amended by 2007/47/EC, and Clauses and Subclauses of this standard

No.	Essential Requirement	Coverage
I.		
1.	General Guidance note 2 and 3 shall be observed	
1	The devices must be designed and manufactured in such a way that, when used under the conditions and for the purposes intended, they will not compromise the clinical condition or the safety of patients, or the safety and health of users or, where applicable, other persons, provided that any risks which may be associated with their intended use constitute acceptable risks when weighed against the benefits to the patient and are compatible with a high level of protection of health and safety. This shall include:	Not completely covered But If the manufacturer follows this standard in his design and manufacturing process, this European Standard gives a valuable set of technical requirements to assist in fulfilling this ER for equipment in the scope of this standard.
	- reducing, as far as possible, the risk of use error due to the ergonomic features of the device and the environment in which the device is intended to be used (design for patient safety), and	Not covered See EN/IEC 60601-1-6, EN/IEC 62366, EN/IEC 60601-1-11 and EN/IEC 60601-1-12
	- consideration of the technical knowledge, experience, education and training and where applicable the medical and physical conditions of intended users (design for lay, professional, disabled or other users).	Covered only for accompanying documents by: 7.9.1 Paragraphs 4 and 5, intended operator
2.	General Guidance note 2 and 3 shall be observed	
2	The solutions adopted by the manufacturer for the design and construction of the devices must conform to safety principles, taking account of the generally acknowledged state of the art. In selecting the most appropriate solutions, the manufacturer must apply the following principles in the following order:	1st paragraph: Covered only in respect of the following and under the condition that 2nd paragraph (including the following 3 bullets) is taken into account: 8 Protection against electrical hazards from ME equipment 9 Protection against mechanical hazards of ME equipment and ME systems 15 Construction of me equipment 2nd paragraph (including the following 3 bullets) Not covered in the normative text.
	- eliminate or reduce risks as far as possible (inherently safe design and construction),	
	- where appropriate take adequate protection measures including alarms if necessary, in relation to risks that cannot be eliminated,	
	- inform users of the residual risks due to any shortcomings of the	

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No.	Essential Requirement	Coverage
	protection measures adopted.	
3	The devices must achieve the performances intended by the manufacturer and be designed, manufactured and packaged in such a way that they are suitable for one or more of the functions referred to in Article 1 (2) (a), as specified by the manufacturer.	Not covered
4	The characteristics and performances referred to in Sections 1, 2 and 3 must not be adversely affected to such a degree that the clinical conditions and safety of the patients and, where applicable, of other persons are compromised during the lifetime of the device as indicated by the manufacturer, when the device is subjected to the stresses which can occur during normal conditions of use.	Not covered However, the standard provides a procedure for the generation of information that is necessary to document that the device is in compliance with this ER.
5.	General Guidance note 2 and 3 shall be observed	
5	The devices must be designed, manufactured and packed in such a way that their characteristics and performances during their intended use will not be adversely affected during transport and storage taking account of the instructions and information provided by the manufacturer.	Covered only in respect of the following: Instructions and information provided by the manufacturer 7.2.17 Marking on protective packaging 7.9.3.1 Technical description 15.3.7 Environmental influences
6.	General Guidance note 2 and 3 shall be observed	
6	Any undesirable side-effect must constitute an acceptable risk when weighed against the performances intended.	Not covered.
6a	Demonstration of conformity with the essential requirements must include a clinical evaluation in accordance with Annex X.	Not covered
II.		
7	**Chemical, physical and biological properties**	General Guidance note 2 and 3 shall be observed
7.1	The devices must be designed and manufactured in such a way as to guarantee the characteristics and performances referred to in Section I (3) on the 'General requirements'. Particular attention must be paid to:	Not covered
	- the choice of materials used, particularly as regards toxicity and, where appropriate, flammability,	Partially covered in respect of the following: Toxicity: 11.7 Biocompatibility, the manufacturer should apply the appropriate part of the EN ISO 10993 series 13.1.2 Emissions, deformation of Enclosure or

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No.	Essential Requirement	Coverage
		exceeding maximum temperature Flammability: 11.2 Fire prevention 11.3 Constructional requirements for fire enclosures 11.4 ME equipment and ME systems intended for use with flammable anaesthetics Annex G Protection against hazards of ignition of flammable anaesthetic mixtures
	- the compatibility between the materials used and biological tissues, cells and body fluids, taking account of the intended purpose of the device,	Not covered The manufacturer should apply the appropriate part of the EN ISO 10993 series
	- where appropriate, the results of biophysical or modeling research whose validity has been demonstrated beforehand.	Not covered
7.2	The devices must be designed, manufactured and packed in such a way as to minimize the risks posed by contaminants and residues to the persons involved in the transport, storage and use of the devices and to the patients, taking account of the intended purpose of the product. Particular attention must be paid to the tissues exposed and to the duration and frequency of exposure.	Not covered
7.3	The devices must be designed and manufactured in such a way that they can be used safely with the materials, substances and gases with which they enter into contact during their normal use or during routine procedures;	Covered only for the physical properties dealt with in Subclauses: 11.2.2 ME equipment and ME systems used in conjunction with oxygen rich environments 11.2.3 Single fault conditions related to oxygen rich environments and 11.6.1, 11.6.2, 11.6.3, 11.6.4, 11.6.6, 11.6.7, 11.6.8 (Overflow, spillage, leakage, cleaning, disinfection, sterilization and compatibility with substances used)
	if the devices are intended to administer medicinal products they must be designed and manufactured in such a way as to be compatible with the medicinal products concerned according to the provisions and restrictions governing these products and that their performance is maintained in accordance with the intended use.	Not covered
7.4	Where a device incorporates, as an integral part, a substance which, if used separately, may be considered to be a	Not covered

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No.	Essential Requirement	Coverage
	medicinal product as defined in Article 1 of Directive 2001/83/EC and which is liable to act upon the body with action ancillary to that of the device, the quality, safety and usefulness of the substance must be verified by analogy with the methods specified in Annex I to Directive 2001/83/EC.	
	For the substances referred to in the first paragraph, the notified body shall, having verified the usefulness of the substance as part of the medical device and taking account of the intended purpose of the device, seek a scientific opinion from one of the competent authorities designated by the Member States or the European Medicines Agency (EMEA) acting particularly through its committee in accordance with Regulation (EC) No 726/2004 on the quality and safety of the substance including the clinical benefit/risk profile of the incorporation of the substance into the device. When issuing its opinion, the competent authority or the EMEA shall take into account the manufacturing process and the data related to the usefulness of incorporation of the substance into the device as determined by the notified body. Where a device incorporates, as an integral part, a human blood derivative, the notified body shall, having verified the usefulness of the substance as part of the medical device and taking into account the intended purpose of the device, seek a scientific opinion from the EMEA, acting particularly through its committee, on the quality and safety of the substance including the clinical benefit/risk profile of the incorporation of the human blood derivative into the device. When issuing its opinion, the EMEA shall take into account the manufacturing process and the data related to the usefulness of incorporation of the substance into the device as determined by the notified body. Where changes are made to an ancillary substance incorporated in a device, in particular related to its manufacturing process, the notified body shall be informed of the changes and shall consult the relevant medicines competent authority (i.e. the one involved in the initial consultation), in	Not covered

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No.	Essential Requirement	Coverage
	order to confirm that the quality and safety of the ancillary substance are maintained. The competent authority shall take into account the data related to the usefulness of incorporation of the substance into the device as determined by the notified body, in order to ensure that the changes have no negative impact on the established benefit/risk profile of the addition of the substance in the medical device. When the relevant medicines competent authority (i.e. the one involved in the initial consultation) has obtained information on the ancillary substance, which could have an impact on the established benefit/risk profile of the addition of the substance in the medical device, it shall provide the notified body with advice, whether this information has an impact on the established benefit/risk profile of the addition of the substance in the medical device or not. The notified body shall take the updated scientific opinion into account in reconsidering its assessment of the conformity assessment procedure.	
7.5	The devices must be designed and manufactured in such a way as to reduce to a minimum the risks posed by substances leaking from the device.	Covered in respect of the following: 9.7 Pressure vessels and parts subject to pneumatic and hydraulic pressure, 11.6.1 Protection against overflow, spillage, leakage, ingress of water or particulate matter, cleaning, disinfection and sterilization, compatibility with substances 11.6.2 Overflow 15.4.9 Oil containers
	Special attention shall be given to substances which are carcinogenic, mutagenic or toxic to reproduction, in accordance with Annex I to Council Directive 67/548/EEC of 27 June 1967 on the approximation of laws, regulations and administrative provisions relating to the classification, packaging and labeling of dangerous substances.	Not covered
	If parts of a device (or a device itself) intended to administer and/or remove medicines, body liquids or other substances to or from the body, or devices intended for transport and storage of such body fluids or substances, contain phthalates which	Not covered

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No.	Essential Requirement	Coverage
	are classified as carcinogenic, mutagenic or toxic to reproduction, of category 1 or 2, in accordance with Annex I to Directive 67/548/EEC, these devices must be labeled on the device itself and/or on the packaging for each unit or, where appropriate, on the sales packaging as a device containing phthalates.	
	If the intended use of such devices includes treatment of children or treatment of pregnant or nursing women, the manufacturer must provide a specific justification for the use of these substances with regard to compliance with the essential requirements, in particular of this paragraph, within the technical documentation and, within the instructions for use, information on residual risks for these patient groups and, if applicable, on appropriate precautionary measures.	Not covered
7.6	Devices must be designed and manufactured in such a way as to reduce, as much as possible, risks posed by the unintentional ingress of substances into the device taking into account the device and the nature of the environment in which it is intended to be used.	Not covered
8	**Infection and microbial contamination**	General Guidance note 2 and 3 shall be observed
8.1	The devices and manufacturing processes must be designed in such a way as to eliminate or reduce as far as possible the risk of infection to the patient, user and third parties. The design must allow easy handling and, where necessary, minimize contamination of the device by the patient or vice versa during use.	Not covered
8.2	Tissues of animal origin must originate from animals that have been subject to veterinary controls and surveillance adapted to the intended use of the tissues.	Not covered
	Notified Bodies shall retain information on the geographical origin of the animals.	Not covered
	Processing, preservation, testing and handling of tissues, cells and substances of animal origin must be carried out so as to provide optimal security. In particular safety with regard to viruses and other *transmissible* agents must be addressed by	Not covered

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No.	Essential Requirement	Coverage
	implementation of validated methods of elimination or viral inactivation in the course of the manufacturing process.	
8.3	Devices delivered in a sterile state must be designed, manufactured and packed in a non-reusable pack and/or according to appropriate procedures to ensure that they are sterile when placed on the market and remain sterile, under the storage and transport conditions laid down, until the protective packaging is damaged or opened.	Not covered
8.4	Devices delivered in a sterile state must have been manufactured and sterilized by an appropriate, validated method.	Not covered
8.5	Devices intended to be sterilized must be manufactured in appropriately controlled (e.g. environmental) conditions.	Not covered
8.6	Packaging system for non-sterile devices must keep the product without deterioration at the level of cleanliness stipulated and, if the devices are to be sterilized prior to use, minimize the risk of microbial contamination;	Covered in respect of 7.2.17 Marking aspects of protective packaging
	the packaging system must be suitable taking account of the method of sterilization indicated by the manufacturer.	Not covered
8.7	The packaging and/or label of the device must distinguish between identical or similar products sold in both sterile and non-sterile condition.	Not covered
9	**Construction and environmental properties**	General Guidance note 2 and 3 shall be observed
9.1	If the device is intended for use in combination with other devices or equipment, the whole combination, including the connection system must be safe and must not impair the specified performances of the devices.	Covered in respect of the following: 9.1 Mechanical hazards 16.3 Power supply 16.5 Separation devices 16.6 Leakage currents 16.8 Interruption of power supply
	Any restrictions on use must be indicated on the label or in the instructions for use.	Covered by 16.2 Accompanying documents of an ME system
9.2	Devices must be designed and manufactured in such a way as to remove or minimize as far as is possible:	
	- the risk of injury, in connection with their physical features, including the volume/pressure ratio, dimensional and where appropriate ergonomic features;	Covered in respect of the following: 8.1 Electric shock 9.1 Mechanical Hazards 10 Radiation (all types) 11.1 Excessive temperatures 11.2 Fire prevention

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No.	Essential Requirement	Coverage
		11.4 Flammable anaesthetics 11.5 Flammable agent 11.6.3 Spillage 11.8 Interruption of power supply 12.4 Hazardous output 13.1 Hazardous situations 13.2 Single Fault condition 15.3 Mechanical strength 15.4 Components and general assembly 15.5.3 Construction of transformers 16.3 Power supply 16.5 Separation devices 16.6 Leakage currents 16.8 Interruption of power supply
	- risks connected with reasonably foreseeable environmental conditions, such as magnetic fields, external electrical influences, electrostatic discharge, pressure, temperature or variations in pressure and acceleration;	Not covered See for EMC EN 60601-1-2 as referenced in Annex ZA See for acceleration EN 60601-1-11 and EN 60601-1-12 as referenced in Annex ZA Covered in respect of the following: pressure, temperature: test in 5.3 according to manufacturers' specification in 7.9.3.1
	- the risks of reciprocal interference with other devices normally used in the investigations or for the treatment given;	Not covered See for EMC EN 60601-1-2 as referenced in annex ZA
	- risks arising where maintenance or calibration are not possible (as with implants), from ageing of materials used or loss of accuracy of any measuring or control mechanism.	Not covered
9.3	Devices must be designed and manufactured in such a way as to minimize the risks of fire or explosion during normal use and in single fault condition.	Covered in respect of the following: Normal use 9.7.5 Pressure vessels, Single fault condition: 11.2 Fire prevention 11.3 Fire enclosures 11.4 Flammable anaesthetics Annex G ignition of flammable anaesthetic mixtures
	Particular attention must be paid to devices whose intended use includes exposure to flammable substances or to substances which could cause combustion.	Covered in respect of the following: 11.4 Flammable anaesthetics Annex G ignition of flammable anaesthetic mixtures
10	**Devices with a measuring function**	
10.1	Devices with a measuring function must be designed and manufactured in such	Not covered

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No.	Essential Requirement	Coverage
	a way as to provide sufficient accuracy and stability within appropriate limits of accuracy and taking account of the intended purpose of the device.	See particular standards EN 60601-2-xx See 12.1 in respect of risks associated with accuracy of controls and instruments
	The limits of accuracy must be indicated by the manufacturer.	Covered by 7.9.3.1 technical description
10.2	The measurement, monitoring and display scale must be designed in line with ergonomic principles, taking account of the intended purpose of the device.	Not covered see EN IEC 60601-1-6 and EN IEC 62366
10.3	The measurements made by devices with a measuring function must be expressed in legal units conforming to the provisions of Council Directive 80/181/EEC.	Covered in respect of the following: 7.4.3 Units of measurement cmH2O is not included in 80/181/EEC
11	**Protection against radiation**	General Guidance note 2 and 3 shall be observed
11.1	General	
11.1.1	Devices shall be designed and manufactured in such a way that exposure of patients, users and other persons to radiation shall be reduced as far as possible compatible with the intended purpose, whilst not restricting the application of appropriate specified levels for therapeutic and diagnostic purposes.	For unintended radiation, covered in respect to the following: 10.1.1 (ionizing radiation), 10.3 (microwave), 10.4 (lasers). For intended radiation, covered in respect to the following: 10.3 (microwave), 10.4 (lasers). Other types of radiation of these devices and other devices not covered. For devices intended to produce radiation see EN 60601-1-3 for diagnostic x-radiation. For other radiation see particular standards EN 60601-2-xx.
11.2	Intended radiation	
11.2.1	Where devices are designed to emit hazardous levels of radiation necessary for a specific medical purpose the benefit of which is considered to outweigh the risks inherent in the emission, it must be possible for the user to control the emissions. Such devices shall be designed and manufactured to ensure reproducibility and tolerance of relevant variable parameters.	1st and 2nd sentence covered in respect of the following: 10.3, Microwave 10.4 Lasers First sentence covered by subclauses 15.4.6, Actuating parts of controls and 15.4.7 hand or foot switches See particular standards EN 60601-2-xx See EN 60601-1-3 for diagnostic x-radiation
11.2.2	Where devices are intended to emit	Not covered.

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No.	Essential Requirement	Coverage
	potentially hazardous, visible and/or invisible radiation, they must be fitted, where practicable, with visual displays and/or audible warnings of such emissions.	
11.3	Unintended radiation	
11.3.1	Devices shall be designed and manufactured in such a way that exposure of patients, users and other persons to the emission of unintended, stray or scattered radiation is reduced as far as possible.	Covered in respect to the following: 10.1.1 (ionizing radiation), 10.3 (microwave), 10.4 (lasers). Other types of radiation of these devices and other devices not covered.
11.4	Instructions	
11.4.1	The operating instructions for devices emitting radiation must give detailed information as to the nature of the emitted radiation, means of protecting the patient and the user and on ways of avoiding misuse and of eliminating the risks inherent in installation.	Covered in respect of information relating to the nature of the emitted radiation: 7.9.2.17 – ME equipment emitting radiation
11.5	Ionizing radiation	
11.5.1	Devices intended to emit ionizing radiation must be designed and manufactured in such a way as to ensure that, where practicable, the quantity, geometry and quality of radiation emitted can be varied and controlled taking into account the intended use.	Not covered For diagnostic x-radiation see EN 60601-1-3. For other devices see particular standards EN 60601-2-xx
11.5.2	Devices emitting ionizing radiation intended for diagnostic radiology shall be designed and manufactured in such a way as to achieve appropriate image and/or output quality for the intended medical purpose whilst minimizing radiation exposure of the patient and user.	Not covered For diagnostic x-radiation see EN 60601-1-3. For other devices see particular standards EN 60601-2-xx
11.5.3	Devices emitting ionizing radiation, intended for therapeutic radiology shall be designed and manufactured in such a way as to enable reliable monitoring and control of the delivered dose, the beam type and energy and where appropriate the quality of radiation.	Not covered
12	**Requirements for medical devices connected to or equipped with an energy source**	General Guidance note 2 and 3 shall be observed
12.1	Devices incorporating electronic programmable systems must be designed to ensure the repeatability, reliability and performance of these systems according to the intended use.	Covered by 14 Programmable electrical medical systems (PEMS)

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No.	Essential Requirement	Coverage
	In the event of a single fault condition (in the system) appropriate means should be adopted to eliminate or reduce as far as possible consequent risks.	
12.1a	For devices which incorporate software or which are medical software in themselves, the software must be validated according to the state of the art taking into account the principles of development lifecycle, risk management, validation and verification.	Covered in respect of devices which incorporate SW by 14 Programmable electrical medical systems (PEMS)
12.2	Devices where the safety of the patients depends on an internal power supply must be equipped with a means of determining the state of the power supply.	Not covered
12.3	Devices where the safety of the patients depends on an external power supply must include an alarm system to signal any power failure.	Not covered
12.4	Devices intended to monitor one or more clinical parameters of a patient must be equipped with appropriate alarm systems to alert the user of situations which could lead to death or severe deterioration of the patient's state of health.	Not covered
12.5	Devices must be designed and manufactured in such a way as to minimize the risks of creating electromagnetic fields which could impair the operation of other devices or equipment in the usual environment.	Not covered EMC: see EN 60601-1-2 as referenced in annex ZA
12.6	Protection against electrical risks	
12.6.1	Devices must be designed and manufactured in such a way as to avoid, as far as possible, the risk of accidental electric shocks during normal use and in single fault condition, provided the devices are installed correctly.	Covered in respect of the following: 6.2 Protection against electric shock 7.2.10 Applied parts 7.9 Accompanying documents 8 Protection against electrical hazard 13.1 Specific hazardous situation 13.2 Single fault conditions 16.6 Leakage currents
12.7	Protection against mechanical and thermal risks	
12.7.1	Devices must be designed and manufactured in such a way as to	Covered in respect of the following: 9.1 Mechanical Hazard

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No.	Essential Requirement	Coverage
	protect the patient and user against mechanical risks connected with, for example, resistance, stability and moving parts.	15.3 Mechanical strength
12.7.2	Devices must be designed and manufactured in such a way as to reduce to the lowest possible level the risks arising from vibration generated by the devices, taking account of technical progress and of the means available for limiting vibrations, particularly at source, unless the vibrations are part of the specified performance.	Covered in respect of the following: 9.6 Acoustic energy and vibration 9.8.1 Support systems
12.7.3	Devices must be designed and manufactured in such a way as to reduce to the lowest possible level the risks arising from the noise emitted, taking account of technical progress and of the means available to reduce noise, particularly at source, unless the noise emitted is part of the specified performance.	Covered in respect of 9.6 Acoustic energy and vibration
12.7.4	Terminals and connectors to the electricity, gas or hydraulic and pneumatic energy supplies which the user has to handle must be designed and constructed in such a way as to minimize all possible risks.	Covered in respect of the following: Electrical Risks: 8.1 Fundamental rule of protection against electric shock 8.2 Connection to power sources 8.4 Limitation of voltage current or energy 8,5 Separation of parts 8.6 Functional earthing 8.7 Leakage current 8.11.3 Power supply cords Gas or Hydraulic and Pneumatic: 9.7 Pressure vessels and parts
12.7.5	Accessible parts of the devices (excluding the parts or areas intended to supply heat or reach given temperatures) and their surroundings must not attain potentially dangerous temperatures under normal use.	Covered by 11.1 Excessive temperatures
12.8	Protection against the risks posed to the patient by energy supplies or substances	
12.8.1	Devices for supplying the patient with energy or substances must be designed and constructed in such a way that the flow-rate can be set and maintained accurately enough to guarantee the safety of the patient and of the user.	Covered in respect of the following: 15.4.2 Temperature and overload control devices 15.4.4 Indicators for standby and output 15.4.6 Actuating parts of controls 15.4.7 Cord-connected hand-held and foot-operated control devices

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No.	Essential Requirement	Coverage
12.8.2	Devices must be fitted with the means of preventing and/or indicating any inadequacies in the flow-rate which could pose a danger.	Covered in respect of the following: 15.4.1 Construction of connectors 15.4.2 Temperature and overload control devices 15.4.4 indicators for standby and output 15.4.5 Pre-set controls 15.4.6 Actuating parts of controls 15.4.7 Cord-connected hand-held and foot-operated control devices
	Devices must incorporate suitable means to prevent, as far as possible, the accidental release of dangerous levels of energy from an energy and/or substance source.	Covered in respect of the following: Energy Source: 12.4 Protection against hazardous output 14 In respect of programmable electrical medical systems (PEMS) 15.4.1 Construction of connectors 15.4.2 Temperature and overload control devices 15.4.4 Indicators for standby and output 15.4.5 Pre-set controls 15.4.6 Actuating parts of controls 15.4.7 Cord-connected hand-held and foot-operated control devices Substance Source: 9.7 Pressure vessels and parts subject to pneumatic and hydraulic pressure 12.4 Protection against hazardous output 14 In respect of programmable electrical medical systems (PEMS) 15.4.4 Indicators for standby and output 15.4.5 Pre-set controls 15.4.6 Actuating parts of controls
12.9	The function of the controls and indicators must be clearly specified on the devices	Covered in respect of the following: 7.4 Marking of controls and instruments
	Where a device bears instructions required for its operation or indicates operating or adjustment parameters by means of a visual system, such information must be understandable to the user and, as appropriate, the patient.	Covered in respect of the following: 7.5 Safety signs 7.9.1 General requirements for accompanying documents
13	**Information supplied by the manufacturer**	
13.1	Each device must be accompanied by the information needed to use it safely and properly, taking account of the training and knowledge of the potential	Covered in respect of the following: 7.2.2 Identification 7.2.4 Accessories

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No.	Essential Requirement	Coverage
	users, and to identify the manufacturer. This information comprises the details on the label and the data in the instructions for use.	7.2.5 Power from other equipment 7.9 Accompanying documents
	As far as practicable and appropriate, the information needed to use the device safely must be set out on the device itself and/or on the packaging for each unit or, where appropriate, on the sales packaging. If individual packaging of each unit is not practicable, the information must be set out in the leaflet supplied with one or more devices.	Covered in respect of the following: 7.2.3 Consult accompanying documents 7.9 Accompanying documents
	Instructions for use must be included in the packaging for every device. By way of exception, no such instructions for use are needed for devices in Class I or IIa if they can be used safely without any such instructions.	Covered in respect of the following: 7.9.1 Accompanying documents, general 7.9.2 Instructions for use
13.2	Where appropriate, this information should take the form of symbols. Any symbol or identification color used must conform to the harmonized standards. In areas for which no standards exist, the symbols and colors must be described in the documentation supplied with the device.	Covered in respect of the following: 7.6 Symbols Annex D Symbols on marking – informative annex for information only
13.3	The label must bear the following particulars: (a) the name or trade name and address of the manufacturer. For devices imported into the Community, in view of their distribution in the Community, the label, or the outer packaging, or instructions for use, shall contain in addition the name and address of the authorized representative where the manufacturer does not have a registered place of business in the Community; (b) the details strictly necessary to identify the device and the contents of the packaging especially for the users; (c) where appropriate, the word 'STERILE'; (d) where appropriate, the batch code, preceded by the word 'LOT', or the serial number; (e) where appropriate, an indication of the date by which the device should be used, in safety,	Covered in respect of the following: a) 7.2.2 Identification (partially covered: in order to comply with this ER, name and address must be used). Std. does not address the specifics of imported devices (authorized representative). b) 7.2.2 Identification (limited to details related to the identification of the device) c) 7.2.17 Protective packaging d) 7.2.2 Identification, 7.2.4 Accessories (the std. does not require to use the word LOT which has to be added) e) 7.2.2 Identification (std. does not specify the format, however, the note directs to a standard that specifies the format) f) 7.2.1 Marking (std. allows three options, manufacturer needs to limit himself on just one) g) Not covered h) Not covered i) 7.2.17 Protective packaging j) 7.2 Marking on the outside of equipment and parts 7.3 Marking on the inside of equipment and parts 7.5 Safety signs k) Covered

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No.	Essential Requirement	Coverage
	expressed as the year and month; (f) where appropriate, an indication that the device is for single use. A manufacturer's indication of single use must be consistent across the Community; (g) if the device is custom-made, the words 'custom-made device'; (h) if the device is intended for clinical investigations, the words 'exclusively for clinical investigations'; (i) any special storage and/or handling conditions; (j) any special operating instructions; (k) any warnings and/or precautions to take; (l) year of manufacture for active devices other than those covered by (e). This indication may be included in the batch or serial number; (m) where applicable, method of sterilization;	7.2.2 Identification 7.2.20 Removable protective means 7.3 Marking on the inside of equipment and parts l) 7.2.2 Identification m) 7.2.17 Protective packaging
	(n) in the case of a device within the meaning of Article 1(4a), an indication that the device contains a human blood derivative.	n) Not covered
13.4	If the intended purpose of the device is not obvious to the user, the manufacturer must clearly state it on the label and in the instructions for use.	Not covered
13.5	Wherever reasonable and practicable, the devices and detachable components must be identified, where appropriate in terms of batches, to allow all appropriate action to detect any potential risk posed by the devices and detachable components.	Covered 7.2.2 Identification
13.6	Where appropriate, the instructions for use must contain the following particulars: (a) the details referred to in Section 13.3, with the exception of (d) and (e); (b) the performances referred to in Section 3 and any undesirable side-effects; (c) if the device must be installed with or connected to other medical devices or equipment in order to operate as required for its intended purpose, sufficient details of its characteristics to identify the	a) Details referred to in Section 13.3, with the exception of (d) and (e);: 13.3 a) Instructions for Use: authorized representative: not covered Instructions for Use: 7.9.2 Instructions for use 13.3 b) Instructions for Use: 7.9.1 General on accompanying documents (for electronic Instructions for Use adhere to EU legislation 2007/12) 13.3 c) Instructions for Use: 7.9.2.18 Equipment and accessories supplied sterile (partly covered, the word "sterile" is not required by the standard) 13.3 d) Exempted for Instructions for Use.

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No.	Essential Requirement	Coverage
	correct devices or equipment to use in order to obtain a safe combination; (d) all the information needed to verify whether the device is properly installed and can operate correctly and safely, plus details of the nature and frequency of the maintenance and calibration needed to ensure that the devices operate properly and safely at all times; (e) where appropriate, information to avoid certain risks in connection with implantation of the device; (f) information regarding the risks of reciprocal interference posed by the presence of the device during specific investigations or treatment; (g) the necessary instructions in the event of damage to the sterile packaging and, where appropriate, details of appropriate methods of re-sterilization;	13.3 e) Exempted for Instructions for Use 13.3 f) Instructions for Use: not covered 13.3 g) Instructions for Use: not covered 13.3 h) Instructions for Use: not covered 13.3 i) Instructions for Use: Covered in respect of the following: 7.9.2.2 Warning and safety notices 7.9.2.18 Equipment and accessories supplied sterile 7.9.3.1 General on Technical description 9.4.4.a Grips and other handling devices Remark: handling is assumed to include installation, but to be different from operating use 13.3 k) Instructions for Use: Covered in respect of the following: 7.9.2.2 Warning and safety notices, first sentence 13.3 l) Instructions for Use: not covered 13.3 m) Instructions for Use: not covered 13.3 n) Instructions for Use: not covered --- b) Performances referred to in Section 3 Not covered c) If the device must be installed with or connected to other medical devices Covered in respect of the following: 7.9.1, General on accompanying documents 7.9.2.1 General on instructions for use 7.9.2.14 Accessories, supplementary equipment, used material 7.9.3, Technical description 14 Programmable electrical medical systems (PEMS) d) Covered in respect of the following: 7.9.2.9 Operating instructions 7.9.2.13 Maintenance e) Not covered f) Not covered g) Covered in respect of the following: 7.2.17 Protective packaging 7.9.2.18 ME equipment and accessories supplied sterile
	(h) if the device is reusable, information on the appropriate processes to allow reuse, including cleaning, disinfection, packaging and, where appropriate, the method of sterilization of the device to be re-sterilized, and any	h) Covered in respect of 7.9.2.12 Cleaning, disinfection and sterilization i) Covered in respect of 7.9 Accompanying documents

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No.	Essential Requirement	Coverage
	restriction on the number of reuses. Where devices are supplied with the intention that they be sterilized before use, the instructions for cleaning and sterilization must be such that, if correctly followed, the device will still comply with the requirements in Section I; If the device bears an indication that the device is for single use, information on known characteristics and technical factors known to the manufacturer that could pose a risk if the device were to be re-used. If in accordance with Section 13.1 no instructions for use are needed, the information must be made available to the user upon request; (i) details of any further treatment or handling needed before the device can be used (for example sterilization, final assembly, etc.); (j) in the case of devices emitting radiation for medical purposes, details of the nature, type, intensity and distribution of this radiation.	j) Covered in respect of 7.9.2.17 ME equipment emitting radiation
	The instructions for use must also include details allowing the medical staff to brief the patient on any contra-indications and any precautions to be taken. These details should cover in particular: (k) precautions to be taken in the event of changes in the performance of the device; (l) precautions to be taken as regards exposure, in reasonably foreseeable environmental conditions, to magnetic fields, external electrical influences, electrostatic discharge, pressure or variations in pressure, acceleration, thermal ignition sources, etc.; (m) adequate information regarding the medicinal product or products which the device in question is designed to administer, including any limitations in the choice of substances to be delivered; (n) precautions to be taken against any special, unusual risks related	k) Not covered l) Not covered m) Not covered n) Not covered o) Not covered p) Not covered q) Not covered

No.	Essential Requirement	Coverage
	to the disposal of the device; (o) medicinal substances, or human blood derivatives incorporated into the device as an integral part in accordance with Section 7.4; (p) degree of accuracy claimed for devices with a measuring function; (q) date of issue or the latest revision of the instructions for use.	

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Annex ZZB
(informative)

Relationship between this European Standard and the Essential Requirements of EU Directive 90/385/EEC on Active Implantable Medical Devices

This European Standard has been prepared under a mandate given to CENELEC by the European Commission and the European Free Trade Association to provide a means of conforming to the Essential Requirements given in Annex I of the EC Directives 90/385/EEC as amended by 2007/47/EC.

General Guidance:

Once this standard will be cited in the Official Journal of the European Union under that Directive, compliance with the clauses of this standard given in Table ZZB.1 confers, within the limits of the scope of this standard, a presumption of conformity with the corresponding Essential Requirements (ERs) of that Directive and associated EFTA regulations.

NOTE 1 This standard is intended to be applied in its entirety only. Selected clauses or subclauses may be not applicable due to the specific type of equipment under consideration. It is necessary to understand and apply Clauses 1 to 16. It is also recommended to understand and apply those clauses which contain general requirements related to a specific subclause. Elements of the standard that are not cited in Table ZZB.1 may be relevant for the appropriate fulfilment of certain essential requirements through indirect reference, and for safety and performance aspects of the device, that are not addressed through essential requirements.

NOTE 2 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 to the AIMD (Directive 90/385/EEC amended by 2007/47/EC). This means that risks have to be reduced "as far as possible", "to a minimum", "to the lowest possible level", "minimized" or "removed", according to the wording of the corresponding essential requirement.

NOTE 3 With respect to Note 4 of clause 4.2.2 General requirement for risk management, the manufacturer's policy for determining **acceptable risk** must be in compliance with essential requirements 1, 2, 5, 6, 7, 8, 9, 11 and 12 of the directive.

NOTE 4 References in the Clauses 3 to 17 or in the Annexes of this standard specify whether the normative references listed in Clause 2 as cited in Annex ZA are to be applied in whole or in part.

NOTE 5 This Annex ZZB is based on Normative References according to Annex ZA, replacing the references in the core text.

WARNING: Other requirements and other EU Directives and Regulations may be applicable to the product(s) falling within the scope of this standard.

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Table ZZB.1 — Relationship between Essential Requirements of Directive 90/385/EEC amended by 2007/47/EC, and Clauses and Subclauses of this standard

No.	Essential Requirement	Coverage
I.	GENERAL REQUIREMENTS	
1.	General Guidance notes 2 and 3 shall be observed	
1	The devices must be designed and manufactured in such a way that, when implanted under the conditions and for the purposes laid down, their use does not compromise the clinical condition or the safety of patients. They must not present any risk to the persons implanting them or, where applicable, to other persons.	Not covered This ER relates to the implanted part of the active implantable medical device.
2	The devices must achieve the performances intended by the manufacturer, viz. be designed and manufactured in such a way that they are suitable for one or more of the functions referred to in Article 1 (2) (a) as specified by him.	Not covered.
3	The characteristics and performances referred to in sections 1 and 2 must not be adversely affected to such a degree that the clinical condition and safety of the patients or, as appropriate, of other persons are compromised during the lifetime of the device anticipated by the manufacturer, where the device is subjected to stresses which may occur during normal conditions of use.	Not covered. However, the standard provides a procedure for the generation of information that is necessary to document that the device is in compliance with this ER with regard to the external parts of an active implantable medical device.
4.	General Guidance notes 2 and 3 shall be observed	
4	The devices must be designed, manufactured and packed in such a way that their characteristics and performances are not adversely affected in the storage and transport conditions laid down by the manufacturer (temperature, humidity, etc.).	Covered for the external part of an active implantable medical device only in respect of the following: 7.2.17 Marking on protective packaging 7.9.3.1 Technical description 15.3.7 Environmental influences
5.	General Guidance notes 2 and 3 shall be observed	
5	Any side effects or undesirable conditions must constitute acceptable risks when weighed against the performances intended.	Not covered.
5a	Demonstration of conformity with the essential requirements must include a clinical evaluation in accordance with Annex 7.	Not covered.

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No.	Essential Requirement	Coverage
II.	**REQUIREMENTS REGARDING DESIGN AND CONSTRUCTION**	
6	The solutions adopted by the manufacturer for the design and construction of the devices must comply with safety principles taking account of the generally acknowledged state of the art.	Covered for the external part of an active implantable medical device only in respect of the following: 8 Protection against electrical hazards from ME equipment 9 Protection against mechanical hazards of ME equipment and ME systems 15 Construction of ME equipment
7	Implantable devices must be designed, manufactured and packed in a non-reusable pack according to appropriate procedures to ensure they are sterile when placed on the market and, in the storage and transport conditions stipulated by the manufacturer, remain so until the packaging is removed and they are implanted.	Not covered.
8.	General Guidance notes 2 and 3 shall be observed	
8	Devices must be designed and manufactured in such a way as to remove or minimize as far as possible:	
	- the risk of physical injury in connection with their physical, including dimensional, features,	Covered for the external part of an active implantable medical device only in respect of the following: 8.1 Electric shock 9.1 Mechanical Hazards 10 Radiation (all types) 11.1 Excessive temperatures 11.2 Fire prevention 11.4 Flammable anaesthetics 11.5 Flammable agent 11.6.3 Spillage 11.8 Interruption of power supply 12.4 Hazardous output 13.1 Hazardous situations 13.2 Single Fault condition 15.3 Mechanical strength 15.4 Components and general assembly 15.5.3 Construction of transformers 16.3 Power supply 16.5 Separation devices 16.6 Leakage currents 16.8 Interruption of power supply

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No.	Essential Requirement	Coverage
	- risks connected with the use of energy sources with particular reference, where electricity is used, to insulation, leakage currents and overheating of the devices,	Covered for the external part of an active implantable medical device only in respect of the following: 8.1 Electric shock 13.2 Single Fault condition 15.5.3 Construction of transformers 16.3 Power supply 16.5 Separation devices 16.6 Leakage currents 16.8 Interruption of power supply
	- risks connected with reasonably foreseeable environmental conditions such as magnetic fields, external electrical influences, electrostatic discharge, pressure or variations in pressure and acceleration,	Not covered See for EMC EN 60601-1-2 as referenced in Annex ZA See for acceleration EN 60601-1-11 and EN 60601-1-12 as referenced in Annex ZA Covered in respect of the following: pressure, temperature: test in 5.3 according to manufacturers' specification in 7.9.3.1
	- risks connected with medical treatment, in particular those resulting from the use of defibrillators or high-frequency surgical equipment,	Covered for the external part of an active implantable medical device only in respect of the following: For defibrillator protection 8.5.5 Defibrillation-proof applied parts
	- risks connected with ionising radiation from radioactive substances included in the device, in compliance with the protection requirements laid down in Council Directive 96/29/Euratom of 13 May 1996 laying down basic safety standards for the protection of the health of workers and the general public against the dangers arising from ionising radiation (1) and Council Directive 97/43/Euratom of 30 June 1997 on health protection of individuals against the dangers of ionising radiation in relation to medical exposure (1),	Not covered.
	- risks which may arise where maintenance and calibration are impossible, including: - excessive increase of leakage currents, - ageing of the materials used, - excess heat generated by the device, - decreased accuracy of any measuring or control mechanism.	Not covered.

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No.	Essential Requirement	Coverage
9	The devices must be designed and manufactured in such a way as to guarantee the characteristics and performances referred to in I. 'General requirements', with particular attention being paid to:	
	- the choice of materials used, particularly as regards toxicity aspects,	Not covered. The manufacturer should apply the appropriate part of EN ISO 10993.
	- mutual compatibility between the materials used and biological tissues, cells and body fluids, account being taken of the anticipated use of the device,	Not covered. The manufacturer should apply the appropriate part of EN ISO 10993.
	- compatibility of the devices with the substances they are intended to administer,	Not covered.
	- the quality of the connections, particularly in respect of safety,	Covered for the external part of an active implantable medical device only in respect of the following: Covered in respect of the following: 15.4.1 Construction of connectors
	- the reliability of the source of energy,	Not covered.
	- if appropriate, that they are leakproof,	Covered for the external part of an active implantable medical device only in respect of the following: 9.7 Pressure vessels and parts subject to pneumatic and hydraulic pressure, 11.6.1 Protection against overflow, spillage, leakage, ingress of water or particulate matter, cleaning, disinfection and sterilization, compatibility with substances 11.6.2 Overflow 15.4.9 Oil containers
	- proper functioning of the programming and control systems, including software. For devices which incorporate software or which are medical software in themselves, the software must be validated according to the state of the art taking into account the principles of development lifecycle, risk management, validation and verification	Covered for the external part of an active implantable medical device which incorporates software by 14 Programmable electrical medical systems (PEMS)
10	- Where a device incorporates, as an integral part, a substance which, if used separately, may be considered to be a medicinal product as defined in Article 1 of Directive 2001/83/EC, and which is liable to act upon the body with action ancillary to that of the device, the quality, safety and usefulness of the substance must be verified by analogy with the methods specified in Annex I to	Not covered.

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No.	Essential Requirement	Coverage
	Directive 2001/83/EC. For the substances referred to in the first paragraph, the notified body shall, having verified the usefulness of the substance as part of the medical device and taking account of the intended purpose of the device, seek a scientific opinion from one of the competent authorities designated by the Member States or the European Medicines Agency (EMEA) acting particularly through its committee in accordance with Regulation (EC) No 726/2004 (2) on the quality and safety of the substance including the clinical benefit/risk profile of the incorporation of the substance into the device. When issuing its opinion, the competent authority or the EMEA shall take into account the manufacturing process and the data related to the usefulness of incorporation of the substance into the device as determined by the notified body. Where a device incorporates, as an integral part, a human blood derivative, the notified body shall, having verified the usefulness of the substance as part of the device and taking account of the intended purpose of the device, seek a scientific opinion from the EMEA, acting particularly through its committee, on the quality and safety of the substance, including the clinical benefit/risk profile of the incorporation of the human blood derivative into the device. When issuing its opinion, the EMEA shall take into account the manufacturing process and the data related to the usefulness of incorporation of the substance into the device as determined by the notified body. Where changes are made to an ancillary substance incorporated in a device, in particular related to its manufacturing process, the notified body shall be informed of the changes and shall consult the relevant medicines competent authority (i.e. the one involved in the initial consultation), in order to confirm that the quality and safety of the ancillary substance are maintained. The competent authority shall take into account the data related to the usefulness of the incorporation of the substance into the device as determined by the notified body, in order to ensure that the changes have no negative impact on the established benefit/risk profile of the addition of the substance in the device. When the relevant medicines competent authority (i.e. the one involved in the initial	

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No.	Essential Requirement	Coverage
	consultation) has obtained information on the ancillary substance, which could have an impact on the established benefit/risk profile of the addition of the substance to the device, it shall provide the notified body with advice, whether this information has an impact on the established benefit/risk profile of the addition of the substance to the device or not. The notified body shall take the updated scientific opinion into account in reconsidering its assessment of the conformity assessment procedure.	
11	The devices and, if appropriate, their component parts must be identified to allow any necessary measure to be taken following the discovery of a potential risk in connection with the devices and their component parts.	Not covered.
12	Devices must bear a code by which they and their manufacturer can be unequivocally identified (particularly with regard to the type of device and year of manufacture); it must be possible to read this code, if necessary, without the need for a surgical operation.	Not covered.
13	When a device or its accessories bear instructions required for the operation of the device or indicate operating or adjustment parameters, by means of a visual system, such information must be understandable to the user and, as appropriate, the patient.	Covered for the external part of an active implantable medical device only in respect of the following: 7.5 Safety signs 7.9.1 General requirements for accompanying documents
14	Every device must bear, legibly and indelibly, the following particulars, where appropriate in the form of generally recognized symbols:	
14.1	On the sterile pack:	Not covered.
	- the method of sterilization,	Not covered.
	- an indication permitting this packaging to be recognized as such,	Not covered.
	- the name and address of the manufacturer,	Not covered.
	- a description of the device,	Not covered.
	- if the device is intended for clinical investigations, the words: ‘exclusively for clinical investigations	Not covered.
	- if the device is custom-made, the words ‘custom-made device’,	Not covered.
	- a declaration that the implantable device is in a sterile condition,	Not covered.
	- the month and year of manufacture,	Not covered.
	- an indication of the time limit for implanting a device safely.	Not covered.

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No.	Essential Requirement	Coverage
14.2	On the sales packaging:	Not covered.
	- the name and address of the manufacturer and the name and address of the authorised representative, where the manufacturer does not have a registered place of business in the Community,	Not covered.
	- a description of the device,	Not covered.
	- the purpose of the device,	Not covered.
	- the relevant characteristics for its use,	Not covered.
	- if the device is intended for clinical investigations, the words: 'exclusively for clinical investigations',	Not covered.
	- if the device is custom-made, the words: 'custom-made device',	Not covered.
	- a declaration that the implantable device is in a sterile condition,	Not covered.
	- the month and year of manufacture,	Not covered.
	- an indication of the time limit for implanting a device safely,	Not covered.
	- the conditions for transporting and staring the device,	Not covered.
	- in the case of a device within the meaning of Article 1(4a), an indication that the device contains a human blood derivative.	Not covered.
15	When placed on the market, each device must be accompanied by instructions for use giving the following particulars:	Not covered.
	- the year of authorization to affix the CE mark,	Not covered.
	- the details referred to in 14.1 and 14.2, with the exception of those referred to in the eighth and ninth indents,	Not covered.
	- the performances referred to in section 2 and any undesirable side effects,	Not covered.
	- information allowing the physician to select a suitable device and the corresponding software and accessories,	Not covered.
	- information constituting the instructions for use allowing the physician and, where appropriate, the patient to use the device, its accessories and software correctly, as well as information on the nature, scope and times for operating controls and trials and, where appropriate, maintenance measures,	Not covered.
	- information allowing, if appropriate, certain risks in connection with implantation of the device to be avoided,	Not covered.

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No.	Essential Requirement	Coverage
	- information regarding the risks of reciprocal interference (1) in connection with the presence of the device during specific investigations or treatment,	Not covered.
	- the necessary instructions in the event of the sterile pack being damaged and, where appropriate, details of appropriate methods of resterilization,	Not covered.
	- an indication, if appropriate, that a device can be reused only if it is reconditioned under the responsibility of the manufacturer to comply with the essential requirements.	Not covered.
	The instruction leaflet must also include details allowing the physician to brief the patient on the contra-indications and the precautions to be taken. These details should cover in particular:	Not covered.
	- information allowing the lifetime of the energy source to be established,	Not covered.
	- precautions to be taken should changes occur in the device's performance,	Not covered.
	- precautions to be taken as regards exposure, in reasonably foreseeable environmental conditions, to magnetic fields, external electrical influences, electrostatic discharge, pressure or variations in pressure, acceleration, etc.,	Not covered.
	- adequate information regarding the medicinal products which the device in question is designed to administer,	Not covered.
	- date of issue or the latest revision of the instructions for use.	Not covered.
16	Confirmation that the device satisfies the requirements in respect of characteristics and performances, as referred to in I. ‘General requirements’, in normal conditions of use, and the evaluation of the side effects or undesirable effects must be based on clinical data established in accordance with Annex 7.	Not covered.

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INTRODUCTION

In 1976, IEC subcommittee 62A published the first edition of IEC/TR 60513, *Basic aspects of the safety philosophy for electrical equipment used in medical practice*. The first edition of IEC/TR 60513 provided the basis for developing:

– the first edition of IEC 60601-1 (the parent safety standard for MEDICAL ELECTRICAL EQUIPMENT);

– the IEC 60601-1-xx series of collateral standards for MEDICAL ELECTRICAL EQUIPMENT;

– the IEC 60601-2-xx series of particular standards for particular types of MEDICAL ELECTRICAL EQUIPMENT; and

– the IEC 60601-3-xx series of performance standards for particular types of MEDICAL ELECTRICAL EQUIPMENT.

Aware of the need and the urgency for a standard covering electrical equipment used in medical practice, the majority of National Committees voted in 1977 in favour of the first edition of IEC 60601-1, based on a draft that at the time represented a first approach to the problem. The extent of the scope, the complexity of the equipment concerned, and the specific nature of some of the protective measures and the corresponding tests for verifying them, required years of effort in order to prepare this first standard, which can now be said to have served as a universal reference since its publication.

However, the frequent application of the first edition revealed room for improvement. These improvements were all the more desirable in view of the considerable success that this standard has enjoyed since its publication.

The careful work of revision subsequently undertaken and continued over a number of years resulted in the publication of the second edition in 1988. This edition incorporated all the improvements that could be reasonably expected up to that time. Further developments remained under constant study. The second edition was amended in 1991 and then again in 1995.

The original IEC approach was to prepare separate BASIC SAFETY and performance standards for MEDICAL ELECTRICAL EQUIPMENT. This was a natural extension of the historical approach taken at the national and international level with other electrical equipment standards (e.g. those for domestic equipment), where BASIC SAFETY is regulated through mandatory standards but other performance specifications are regulated by market pressure. In this context, it has been said that, “The ability of an electric kettle to boil water is not critical to its safe use!”

It is now recognized that this is not the situation with many items of MEDICAL ELECTRICAL EQUIPMENT, and RESPONSIBLE ORGANIZATIONS have to depend on standards to ensure ESSENTIAL PERFORMANCE as well as BASIC SAFETY. Such areas include the accuracy with which the equipment controls the delivery of energy or therapeutic substances to the PATIENT, or processes and displays physiological data that will affect PATIENT management.

This recognition means that separating BASIC SAFETY and performance is somewhat inappropriate in addressing the HAZARDS that result from inadequate design of MEDICAL ELECTRICAL EQUIPMENT. Many particular standards in the IEC 60601-2-xx series address a range of ESSENTIAL PERFORMANCE requirements that cannot be directly evaluated by the RESPONSIBLE ORGANIZATION without applying such standards. (However, the current IEC 60601 series includes fewer requirements for ESSENTIAL PERFORMANCE than for BASIC SAFETY).

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In anticipation of a third edition of IEC 60601-1, IEC subcommittee 62A prepared a second edition of IEC/TR 60513 [12] [1)] in 1994. It was intended that the second edition of IEC/TR 60513 would provide guidance for developing this edition of IEC 60601-1, and for the further development of the IEC 60601-1-xx and IEC 60601-2-xx series.

In order to achieve consistency in international standards, address present expectations in the health care community and align with developments in IEC 60601-2-xx, the second edition of IEC/TR 60513 includes two major new principles:

– the first change is that the concept of "SAFETY" has been broadened from the BASIC SAFETY considerations in the first and second editions of IEC 60601-1 to include ESSENTIAL PERFORMANCE matters, (e.g. the accuracy of physiological monitoring equipment). Application of this principle leads to the change of the title of this publication from "Medical electrical equipment, Part 1: General requirements for safety" in the second edition, to "Medical electrical equipment, Part 1: General requirements for basic safety and essential performance";

– the second change is that, in specifying minimum safety requirements, provision is made for assessing the adequacy of the design PROCESS when this is the only practical method of assessing the safety of certain technologies such as programmable electronic systems. Application of this principle is one of the factors leading to introduction of a general requirement to carry out a RISK MANAGEMENT PROCESS. In parallel with the development of the third edition of IEC 60601-1, a joint project with ISO/TC 210 resulted in the publication of a general standard for RISK MANAGEMENT of medical devices. ⟦A1⟩ Compliance with this edition of IEC 60601-1 requires that the MANUFACTURER have in place a RISK MANAGEMENT PROCESS complying with parts of ISO 14971 (see 4.2). ⟨A1⟧

This standard contains requirements concerning BASIC SAFETY and ESSENTIAL PERFORMANCE that are generally applicable to MEDICAL ELECTRICAL EQUIPMENT. For certain types of MEDICAL ELECTRICAL EQUIPMENT, these requirements are either supplemented or modified by the special requirements of a collateral or particular standard. Where particular standards exist, this standard should not be used alone.

⟦A1⟩ Amendment 1 to this standard is intended to address:

– issues identified by National Committees and other interested parties since the publication of IEC 60601-1:2005;

– the way in which RISK MANAGEMENT has been introduced into IEC 60601-1:2005; and

– the way the concept of ESSENTIAL PERFORMANCE is used in IEC 60601-1:2005. ⟨A1⟧

1) Figures in square brackets refer to the Bibliography.

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MEDICAL ELECTRICAL EQUIPMENT –

Part 1: General requirements for basic safety and essential performance

1 Scope, object and related standards

1.1 * Scope

This International Standard applies to the BASIC SAFETY and ESSENTIAL PERFORMANCE of MEDICAL ELECTRICAL EQUIPMENT and MEDICAL ELECTRICAL SYSTEMS, hereafter referred to as ME EQUIPMENT and ME SYSTEMS.

If a clause or subclause is specifically intended to be applicable to ME EQUIPMENT only, or to ME SYSTEMS only, the title and content of that clause or subclause will say so. If that is not the case, the clause or subclause applies both to ME EQUIPMENT and to ME SYSTEMS, as relevant.

HAZARDS inherent in the intended physiological function of ME EQUIPMENT or ME SYSTEMS within the scope of this standard are not covered by specific requirements in this standard except in 7.2.13 and 8.4.1.

〈A1〉 NOTE 1 〈A1〉 See also 4.2.

〈A1〉 *text deleted* 〈A1〉

〈A1〉 The IEC 60601 series does not apply to:

– in vitro diagnostic equipment that does not fall within the definition of ME EQUIPMENT, which is covered by the IEC 61010 series [61];

– implantable parts of active implantable medical devices covered by the ISO 14708 series [69]; or

– medical gas pipeline systems covered by ISO 7396-1 [68].

NOTE 2 ISO 7396-1 applies the requirement of IEC 60601-1-8 to certain monitoring and ALARM SIGNALS. 〈A1〉

1.2 Object

The object of this standard is to specify general requirements and to serve as the basis for particular standards.

1.3 * Collateral standards

In the IEC 60601 series, collateral standards specify general requirements for BASIC SAFETY and ESSENTIAL PERFORMANCE applicable to:

– a subgroup of ME EQUIPMENT (e.g. radiological equipment);

– a specific characteristic of all ME EQUIPMENT not fully addressed in this standard.

Applicable collateral standards become normative at the date of their publication and shall apply together with this standard.

NOTE 1 When evaluating compliance with IEC 60601-1, it is permissible to independently assess compliance with the collateral standards.