Elektrilised meditsiiniseadmed. Osa 1: Üldised nõuded esmasele ohutusele ja olulistele toimimisnäitajatele

Medical electrical equipment - Part 1: General requirements for basic safety and essential performance

EESTI STANDARDIKESKUS
ESTONIAN CENTRE FOR STANDARDISATION

EESTI STANDARDI EESSÕNA

NATIONAL FOREWORD

See Eesti standard EVS-EN 60601-1:2006+A11:2011+A1:2013 sisaldab Euroopa standardi EN 60601-1:2006 + AC:2010 + A11:2011 + A1:2013 + AC:2014 ingliskeelset teksti.	This Estonian standard EVS-EN 60601-1:2006+A11:2011+A1:2013 consists of the English text of the European standard EN 60601-1:2006 + AC:2010 + A11:2011 + A1:2013 + AC:2014.
Standard on jõustunud sellekohase teate avaldamisega EVS Teatajas.	This standard has been endorsed with a notification published in the official bulletin of the Estonian Centre for Standardisation.
Euroopa standardimisorganisatsioonid on teinud Euroopa standardi rahvuslikele liikmetele kättesaadavaks 01.01.2007.	Date of Availability of the European standard is 01.01.2007.
Standard on kättesaadav Eesti Standardikeskusest.	The standard is available from the Estonian Centre for Standardisation.

Tagasisidet standardi sisu kohta on võimalik edastada, kasutades EVS-i veebilehel asuvat tagasiside vormi või saates e-kirja meiliaadressile standardiosakond@evs.ee.

ICS 11.040

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN 60601-1

October 2006

ICS 11.040

Supersedes EN 60601-1:1990 + amendments
Incorporates corrigendum March 2010

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

Central Secretariat: rue de Stassart 35, B - 1050 Brussels

Ref. No. EN 60601-1:2006 E

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.

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.

In the official version, for Bibliography, the following notes have to be added for the standards indicated:

IEC 60073	NOTE	Harmonized as EN 60073:2002 (not modified).
IEC 60086-1	NOTE	Harmonized as EN 60086-1:2001 (not modified).
IEC 60127-6	NOTE	Harmonized as EN 60127-6:1994 (not modified).
IEC 60309-1	NOTE	Harmonized as EN 60309-1:1999 (not modified).
IEC 60317-43	NOTE	Harmonized as EN 60317-43:1997 (not modified).
IEC 60601-1-1	NOTE	Harmonized as EN 60601-1-1:2001 (not modified).
IEC 60601-1-4	NOTE	Harmonized as EN 60601-1-4:1996 + A1:1999 (not modified).
IEC 60601-2-49	NOTE	Harmonized as EN 60601-2-49:2001 (not modified).
IEC 60695-1-1	NOTE	Harmonized as EN 60695-1-1:2000 (not modified).
IEC 60721 series	NOTE	Harmonized in EN 60721 series (not modified).
IEC 60990	NOTE	Harmonized as EN 60990:1999 (not modified).
IEC 61000-4-11	NOTE	Harmonized as EN 61000-4-11:2004 (not modified).
IEC 61010-1	NOTE	Harmonized as EN 61010-1:2001 (not modified).
IEC 61140	NOTE	Harmonized as EN 61140:2002 (not modified).
IEC 62079	NOTE	Harmonized as EN 62079:2001 (not modified).
IEC 62304	NOTE	Harmonized as EN 62304:2006 (not modified).
ISO 407	NOTE	Harmonized as EN ISO 13407:2004 (not modified).
ISO 8041	NOTE	Harmonized as EN ISO 8041:2005 (not modified).
ISO 13485	NOTE	Harmonized as EN ISO 13485:2003 (not modified).

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Endorsement notice

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

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

Annex ZA
(normative)

Normative references to international publications with their corresponding European publications

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

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

Publication	Year	Title	EN/HD	Year
IEC 60065 (mod)	2001	Audio, video and similar electronic apparatus - Safety requirements	EN 60065 + corr. March	2002 2006
IEC 60068-2-2	1974	Environmental testing	EN 60068-2-2 [1]	1993
A1	1993	Part 2: Tests - Tests B: Dry heat	A1	1993
A2	1994		A2	1994
IEC 60079-0 (mod)	- [2]	Electrical apparatus for explosive gas atmospheres Part 0: General requirements	EN 60079-0	2006 [3]
IEC 60079-2	- [2]	Electrical apparatus for explosive gas atmospheres Part 2: Pressurized enclosures "p"	EN 60079-2 + corr. April	2004 [3] 2006
IEC 60079-5	- [2]	Electrical apparatus for explosive gas atmospheres Part 5: Powder filling 'q'	-	-
IEC 60079-6	- [2]	Electrical apparatus for explosive gas atmospheres Part 6: Oil-immersion "o"	-	-
IEC 60083	- [2]	Plugs and socket-outlets for domestic and similar general use standardized in member countries of IEC	-	-
IEC 60085	- [2]	Electrical insulation - Thermal classification	EN 60085	2004 [3]
IEC 60086-4	- [2]	Primary batteries Part 4: Safety of lithium batteries	EN 60086-4	2000 [3]
IEC 60112	- [2]	Method for the determination of the proof and the comparative tracking indices of solid insulating materials	EN 60112	2003 [3]
IEC 60127-1	2006	Miniature fuses Part 1: Definitions for miniature fuses and general requirements for miniature fuse-links	EN 60127-1	2006
IEC 60227-1 [4]	1993	Polyvinyl chloride insulated cables of rated	-	-
A1	1995	voltages up to and including 450/750 V	-	-
A2	1998	Part 1: General requirements	-	-

[1] EN 60068-2-2 includes supplement A:1976 to IEC 60068-2-2.

[2] Undated reference.

[3] Valid edition at date of issue.

[4] 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.

Publication	Year	Title	EN/HD	Year
IEC 60245-1 [5)]	2003	Rubber insulated cables - Rated voltages up to and including 450/750 V Part 1: General requirements	-	-
IEC 60252-1	- [2)]	AC motor capacitors Part 1: General - Performance, testing and rating - Safety requirements - Guide for installation and operation	EN 60252-1	2001 [3)]
IEC 60320-1	- [2)]	Appliance couplers for household and similar general purposes Part 1: General requirements	EN 60320-1	2001 [3)]
IEC 60335-1 (mod)	2001	Household and similar electrical appliances - Safety Part 1: General requirements	EN 60335-1 A11 A12 + corr. July	2002 2004 2006 2006
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	-	-
IEC 60445	- [2)]	Basic and safety principles for man-machine interface, marking and identification - Identification of equipment terminals and of terminations of certain designated conductors, including general rules for an alphanumeric system	EN 60445	2000 [3)]
IEC 60447	- [2)]	Basic and safety principles for man-machine interface, marking and identification - Actuating principles	EN 60447	2004 [3)]
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	- [2)]	Medical electrical equipment Part 1-2: General requirements for safety - Collateral standard: Electromagnetic compatibility - Requirements and tests	EN 60601-1-2	2001 [3)]
IEC 60601-1-3	- [2)]	Medical electrical equipment Part 1: General requirements for safety - 3. Collateral standard: General requirements for radiation protection in diagnostic X-ray equipment	EN 60601-1-3	1994 [3)]
IEC 60601-1-6	- [2)]	Medical electrical equipment Part 1-6: General requirements for safety - Collateral standard: Usability	EN 60601-1-6	2004 [3)]

[5)] 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.

Publication	Year	Title	EN/HD	Year
IEC 60601-1-8	- [2)]	Medical electrical equipment Part 1-8: General requirements for safety - Collateral standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems	EN 60601-1-8 + corr. October	2004 [3)] 2006
IEC 60664-1 (mod) + A1 + A2	1992 2000 2002	Insulation coordination for equipment within low-voltage systems Part 1: Principles, requirements and tests	EN 60664-1	2003
IEC 60695-11-10	- [2)]	Fire hazard testing Part 11-10: Test flames - 50 W horizontal and vertical flame test methods	EN 60695-11-10	1999 [3)]
IEC 60730-1 (mod) A1 (mod)	1999 2003	Automatic electrical controls for household and similar use Part 1: General requirements	EN 60730-1 A12 A1 A13 A14	2000 2003 2004 2004 2005
IEC 60825-1 A1 A2	1993 1997 2001	Safety of laser products Part 1: Equipment classification, requirements and user's guide	EN 60825-1 + corr. February A1 A2 + corr. April	1994 1995 2002 2001 2004
IEC 60851-3 A1 A2	1996 1997 2003	Winding wires - Test methods Part 3: Mechanical properties	EN 60851-3 A1 A2	1996 1997 2003
IEC 60851-5 A1 A2	1996 1997 2004	Winding wires - Test methods Part 5: Electrical properties	EN 60851-5 A1 A2	1996 1997 2004
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 60884-1	- [2)]	Plugs and socket-outlets for household and similar purposes Part 1: General requirements	-	-
IEC 60950-1 (mod)	2001	Information technology equipment - Safety Part 1: General requirements	EN 60950-1 [6)] + corr. April A11	2001 2004 2004
IEC 61058-1 (mod) + A1	2000 2001	Switches for appliances Part 1: General requirements	EN 61058-1	2002
IEC 61558-1 (mod) A1	1997 1998	Safety of power transformers, power supply units and similar Part 1: General requirements and tests	EN 61558-1 [7)] + corr. April A1 A11	1997 2003 1998 2003
IEC 61558-2-1	- [2)]	Safety of power transformers, power supply units and similar Part 2-1: Particular requirements for separating transformers for general use	EN 61558-2-1	1997 [3)]
IEC 61672-1	- [2)]	Electroacoustics - Sound level meters Part 1: Specifications	EN 61672-1	2003 [3)]

[6)] EN 60950-1 is superseded by EN 60950-1:2006, which is based on IEC 60950-1:2005, mod.

[7)] EN 61558-1 is superseded by EN 61558-1:2005, which is based on IEC 61558-1:2005.

Publication	Year	Title	EN/HD	Year
IEC 61672-2	- [2)]	Electroacoustics - Sound level meters Part 2: Pattern evaluation tests	EN 61672-2	2003 [3)]
IEC 61965	- [2)]	Mechanical safety of cathode ray tubes	EN 61965	2003 [3)]
ISO 31	Series	Quantities and units of space and time	-	-
ISO 780	- [2)]	Packaging - Pictorial marking for handling of goods	EN ISO 780	1999
ISO 1000	- [2)]	SI units and recommendations for the use of their multiples and of certain other units	-	-
ISO 1853	- [2)]	Conducting and dissipative rubbers, vulcanized or thermoplastic - Measurement of resistivity	-	-
ISO 2878	- [2)]	Rubber, vulcanized - Antistatic and conductive products - Determination of electrical resistance	-	-
ISO 2882	- [2)]	Rubber, vulcanized - Antistatic and conductive products for hospital use - Electrical resistance limits	-	-
ISO 3746	- [2)]	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	1995
ISO 3864-1	2002	Graphical symbols - Safety colours and safety signs Part 1: Design principles for safety signs in workplaces and public areas	-	-

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Annex ZZ
(informative)

Coverage of Essential Requirements of EC Directives

This European Standard has been prepared under a mandate given to CENELEC by the European Commission and the European Free Trade Association and within its scope the standard covers all relevant essential requirements as given in Annex I of the EC Directives 90/385/EEC and 93/42/EEC.

Compliance with this standard provides one means of conformity with the specified essential requirements of the Directives concerned.

WARNING: Other requirements and other EC Directives may be applicable to the products falling within the scope of this standard.

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EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN 60601-1/A11

October 2011

ICS 11.040

English version

Medical electrical equipment - Part 1: General requirements for basic safety and essential performance

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

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

This amendment A11 modifies the European Standard EN 60601-1:2006; it was approved by CENELEC on 2011-10-01. CENELEC members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for giving this amendment the status of a national standard without any alteration.

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

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

CENELEC members are the national electrotechnical committees of Austria, Belgium, Bulgaria, Croatia, 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

Management Centre: Avenue Marnix 17, B - 1000 Brussels

Ref. No. EN 60601-1:2006/A11:2011 E

Foreword

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.

Replace *Annex ZZ of EN 60601-1:2006 by:*

Annex ZZA
(informative)

Coverage of Essential Requirements of EC Directives

This European Standard has been prepared under a mandate given to CENELEC by the European Commission and the European Free Trade Association and within its scope the standard covers all relevant essential requirements as given in Annex I of the EC Directive 93/42/EEC except the following:

– Essential Requirement 6a

– Essential Requirement 7.4

– Essential Requirement 7.5 paragraph 2 & 3

– Essential Requirement 13.6 (q)

Compliance with this standard provides one means of conformity with the specified essential requirements of the Directives concerned.

WARNING: Other requirements and other EC Directives may be applicable to the products falling within the scope of this standard.

Annex ZZB
(informative)

Coverage of Essential Requirements of EC Directives

This European Standard has been prepared under a mandate given to CENELEC by the European Commission and the European Free Trade Association and within its scope the standard covers all relevant essential requirements as given in Annex I of the EC Directive 90/385/EEC except the following:

– Essential Requirement 5a

– Essential Requirement 7

– Essential Requirement 8 bullet 5

– Essential Requirement 10

– Essential Requirement 11

– Essential Requirement 12

– Essential Requirement 14

– Essential Requirement 15

– Essential Requirement 16

Compliance with this standard provides one means of conformity with the specified essential requirements of the Directives concerned.

WARNING: Other requirements and other EC Directives may be applicable to the products falling within the scope of this standard.

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EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN 60601-1/A1

October 2013

ICS 11.040

English version

Medical electrical equipment - Part 1: General requirements for basic safety and essential performance

(IEC 60601-1:2005/A1:2012)

Appareils électromédicaux - Partie 1: Exigences générales pour la sécurité de base et les performances essentielles (CEI 60601-1:2005/A1:2012)

Medizinische elektrische Geräte - Teil 1: Allgemeine Festlegungen für die Sicherheit einschließlich der wesentlichen Leistungsmerkmale (IEC 60601-1:2005/A1:2012)

This amendment A1 modifies the European Standard EN 60601-1:2006; it was approved by CENELEC on 2013-09-24. CENELEC members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for giving this amendment the status of a national standard without any alteration.

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

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

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

CENELEC

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

CEN-CENELEC Management Centre: Avenue Marnix 17, B - 1000 Brussels

Ref. No. EN 60601-1:2006/A1:2013 E

Foreword

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.

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).
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.

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.

Replace *Annex ZA of EN 60601-1:2006 by :*

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.

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		
A1	1995			
A2	1998	Part 1: General requirements	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.

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	1996	Winding wires - Test methods	EN 60851-6	1996
A1	1997	Part 6: Thermal properties	A1	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)	2000	Switches for appliances		
A1	2001	Part 1: General requirements	EN 61058-1	2002
A2	2007		A2	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

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

Publication	Year	Title	EN/HD and IEC/ISO	Year
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
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

Publication	Year	Title	EN/HD and IEC/ISO	Year
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
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

Annex ZZ
(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 ZZ.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 ZZ.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 ZZ 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.

Table ZZ.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	

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

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

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

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

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

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