SLOVENSKI STANDARD
SIST EN 60601-1:2007/A1:2014

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Nadomešča:
SIST EN 60601-1:2007/A11:2012

Medicinska električna oprema - 1. del: Splošne zahteve za osnovno varnost in bistvene lastnosti - Dopolnilo A1

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

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

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

Ta slovenski standard je istoveten z: **EN 60601-1:2006/A1:2013**

ICS:

11.040.01	Medicinska oprema na splošno	Medical equipment in general

SIST EN 60601-1:2007/A1:2014 **en**

EUROPEAN STANDARD

NORME EUROPÉENNE

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EN 60601-1/A1

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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 13407.
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	Year
IEC 60065 (mod) + corr. August + A1 (mod) + A2 (mod)	2001 2002 2005 2010	Audio, video and similar electronic apparatus - Safety requirements	EN 60065 + corr. August + A1 + A2 + A11 + A12	2002 2007 2006 2010 2008 2011
IEC 60068-2-2	2007	Environmental testing - Part 2-2: Tests - Test B: Dry heat	EN 60068-2-2	2007
IEC 60079-0	-	Explosive atmospheres - Part 0: Equipment - General requirements	EN 60079-0	-
IEC 60079-2	-	Explosive atmospheres - Part 2: Equipment protection by pressurized enclosure "p"	EN 60079-2	-
IEC 60079-5	-	Explosive atmospheres - Part 5: Equipment protection by powder filling "q"	EN 60079-5	-
IEC 60079-6	-	Explosive atmospheres - Part 6: Equipment protection by oil immersion "o"	EN 60079-6	2007
IEC 60083	-	Plugs and socket-outlets for domestic and similar general use standardized in member countries of IEC	-	-
IEC 60085	-	Electrical insulation - Thermal evaluation and designation	EN 60085	-
IEC 60086-4	-	Primary batteries - Part 4: Safety of lithium batteries	EN 60086-4	-
IEC 60112	-	Method for the determination of the proof and the comparative tracking indices of solid insulating materials	EN 60112	-
IEC 60127-1	-	Miniature fuses - Part 1: Definitions for miniature fuses and general requirements for miniature fuse-links	EN 60127-1	-
IEC 60227-1	2007	Polyvinyl chloride insulated cables of rated voltages up to and including 450/750 V - Part 1: General requirements	-	-
IEC 60245-1 + A1	2003 2007	Rubber insulated cables - Rated voltages up to and including 450/750 V - Part 1: General requirements	-	-

Publication	Year	Title	EN/HD	Year
IEC 60252-1	-	AC motor capacitors - Part 1: General - Performance, testing and rating - Safety requirements - Guidance for installation and operation	EN 60252-1	-
IEC 60320-1	-	Appliance couplers for household and similar general purposes - Part 1: General requirements	EN 60320-1	-
IEC 60335-1 (mod) + corr. July + corr. April	2010 2010 2011	Household and similar electrical appliances - Safety - Part 1: General requirements	EN 60335-1	2012
IEC 60364-4-41	-	Low-voltage electrical installations - Part 4-41: Protection for safety - Protection against electric shock	HD 60364-4-41	-
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[1)]	2005
IEC 60417	Data-base	Graphical symbols for use on equipment	-	-
IEC 60445	-	Basic and safety principles for man-machine interface, marking and identification - Identification of equipment terminals, conductor terminations and conductors	EN 60445	-
IEC 60447	-	Basic and safety principles for man-machine interface, marking and identification - Actuating principles	EN 60447	-
IEC 60529 + A1	1989 1999	Degrees of protection provided by enclosures (IP Code)	EN 60529 + corr. May + A1	1991 1993 2000
IEC 60601-1-2	-	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	-
IEC 60601-1-3	-	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	-
IEC 60601-1-6	-	Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability	EN 60601-1-6	-

[1)] EN 60384-14 is superseded by EN 60384-14:2013, which is based on IEC 60384-14:2013.

Publication	Year	Title	EN/HD	Year
IEC 60601-1-8	-	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	-
IEC 60664-1	2007	Insulation coordination for equipment within low-voltage systems - Part 1: Principles, requirements and tests	EN 60664-1	2007
IEC 60695-11-10	-	Fire hazard testing - Part 11-10: Test flames - 50 W horizontal and vertical flame test methods	EN 60695-11-10	-
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[2)] + A1	1996 1997
IEC 60884-1	-	Plugs and socket-outlets for household and similar purposes - Part 1: General requirements	-	-
IEC 60950-1 (mod) + corr. October	2001 2002	Information technology equipment - Safety - Part 1: General requirements	EN 60950-1[3)] + corr. December + A11	2001 2007 2004
IEC 61058-1 (mod) + corr. January + A1 + A2	2000 2009 2001 2007	Switches for appliances - Part 1: General requirements	EN 61058-1[4)] + A2	2002 2008
IEC 61558-2-1	-	Safety of power transformers, power supplies, reactors and similar products - Part 2-1: Particular requirements and tests for separating transformers and power supplies incorporating separating transformers for general applications	EN 61558-2-1	-
IEC 61672-1	-	Electroacoustics - Sound level meters - Part 1: Specifications	EN 61672-1	-
IEC 61672-2	-	Electroacoustics - Sound level meters - Part 2: Pattern evaluation tests	EN 61672-2	-
IEC 61965	-	Mechanical safety of cathode ray tubes	EN 61965	-

[2)] EN 60851-6 is superseded by EN 60851-6:2012, which is based on IEC 60851-6:2012.

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

[4)] EN 61058-1 includes A1 to IEC 61058-1 (mod) + corr. January .

Publication	Year	Title	EN/HD	Year
IEC 62133	-	Secondary cells and batteries containing alkaline or other non-acid electrolytes - Safety requirements for portable sealed secondary cells, and for batteries made from them, for use in portable applications	EN 62133	-
IEC 62304	2006	Medical device software - Software life-cycle processes	EN 62304 + corr. November	2006 2008
ISO 780	-	Packaging - Pictorial marking for handling of goods	EN ISO 780	-
ISO 1853	-	Conducting and dissipative rubbers, vulcanized or thermoplastic - Measurement of resistivity	-	-
ISO 2878	-	Rubber, vulcanized - Antistatic and conductive products - Determination of electrical resistance	-	-
ISO 2882	-	Rubber, vulcanized - Antistatic and conductive products for hospital use - Electrical resistance limits	-	-
ISO 3746	-	Acoustics - Determination of sound power levels and sound energy levels of noise sources using sound pressure - Survey method using an enveloping measurement surface over a reflecting plane	EN ISO 3746	-
ISO 3864-1	2002	Graphical symbols - Safety colours and safety signs - Part 1: Design principles for safety signs in workplaces and public areas	-	-
ISO 5349-1	-	Mechanical vibration - Measurement and evaluation of human exposure to hand-transmitted vibration - Part 1: General requirements	EN ISO 5349-1	-
ISO 7000	2004	Graphical symbols for use on equipment - Index and synopsis	-	-
ISO 7010	2011	Graphical symbols - Safety colours and safety signs - Registered safety signs	-	-
ISO 9614-1	-	Acoustics - Determination of sound power levels of noise sources using sound intensity - Part 1: Measurement at discrete points	EN ISO 9614-1	-
ISO 10993	series	Biological evaluation of medical devices	EN ISO 10993	series
ISO 11135-1	2007	Sterilization of health care products - Ethylene oxide - Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices	EN ISO 11135-1	2007
ISO 11137-1	2006	Sterilization of health care products - Radiation - Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices	EN ISO 11137-1	2006
ISO 13857	2008	Safety of machinery - Safety distances to prevent hazard zones being reached by upper and lower limbs	EN ISO 13857	2008

Publication	Year	Title	EN/HD	Year
ISO 14971	2007	Medical devices - Application of risk management to medical devices	EN ISO 14971	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 17665-1	2006
ISO 23529	-	Rubber - General procedures for preparing and conditioning test pieces for physical test methods	-	-
ISO 80000-1	2009	Quantities and units - Part 1: General	EN ISO 80000-1	2013

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