



# SLOVENSKI STANDARD

## SIST EN 60601-1:2007/A1:2014

01-januar-2014

Nadomešča:

SIST EN 60601-1:2007/A11:2012

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### 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

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#### **ICS:**

|           |                              |                              |
|-----------|------------------------------|------------------------------|
| 11.040.01 | Medicinska oprema na splošno | Medical equipment in general |
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| <b>SIST EN 60601-1:2007/A1:2014</b> | <b>en</b> |
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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  
essentiels  
(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.

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# 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**

## 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.                   |

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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.

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

| <u>Publication</u> | <u>Year</u> | <u>Title</u>  | <u>EN/HD</u>   | <u>Year</u> |
|--------------------|-------------|---|----------------|-------------|
| IEC 60065 (mod)    | 2001        | Audio, video and similar electronic apparatus   | EN 60065       | 2002        |
| + corr. August     | 2002        | - Safety requirements   | + corr. August | 2007        |
| + A1 (mod)         | 2005        |   | + A1           | 2006        |
| + A2 (mod)         | 2010        |   | + A2           | 2010        |
|                    |             |   | + A11          | 2008        |
|                    |             |   | + A12          | 2011        |
| IEC 60068-2-2      | 2007        | Environmental testing -<br>Part 2-2: Tests - Test B: Dry heat   | EN 60068-2-2   | 2007        |
| IEC 60079-0        | -           | Explosive atmospheres -<br>Part 0: Equipment - General requirements   | EN 60079-0     | -           |
| IEC 60079-2        | -           | Explosive atmospheres -<br>Part 2: Equipment protection by pressurized enclosure "p"                                  | EN 60079-2     | -           |
| IEC 60079-5        | -           | Explosive atmospheres -<br>Part 5: Equipment protection by powder filling "q"   | EN 60079-5     | -           |
| IEC 60079-6        | -           | Explosive atmospheres -<br>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 -<br>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 -<br>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 -<br>Part 1: General requirements | -              | -           |
| IEC 60245-1        | 2003        | Rubber insulated cables - Rated voltages up to and including 450/750 V -<br>Part 1: General requirements              | -              | -           |
| + A1               | 2007        |   |                |             |

| <u>Publication</u>                                 | <u>Year</u>          | <u>Title</u>  | <u>EN/HD</u>                    | <u>Year</u>          |
|--|----------------------|---|---------------------------------|----------------------|
| IEC 60252-1  | -                    | AC motor capacitors -<br>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 -<br>Part 1: General requirements   | EN 60320-1                      | -                    |
| IEC 60335-1 (mod)<br>+ corr. July<br>+ corr. April | 2010<br>2010<br>2011 | Household and similar electrical appliances - Safety -<br>Part 1: General requirements  | EN 60335-1                      | 2012                 |
| IEC 60364-4-41                                     | -                    | Low-voltage electrical installations -<br>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 -<br>Part 14: Sectional specification - Fixed capacitors for electromagnetic interference suppression and connection to the supply mains | EN 60384-14 <sup>1)</sup>       | 2005                 |
| IEC 60417  | Data-base            | Graphical symbols for use on equipment  |                                 | -                    |
| IEC 60445  | -                    | Basic and safety principles for man-machine interface, marking and identification -<br>Identification of equipment terminals, conductor terminations and conductors                       | EN 60445                        | -                    |
| IEC 60447  | -                    | Basic and safety principles for man-machine interface, marking and identification -<br>Actuating principles   | EN 60447                        | -                    |
| IEC 60529<br>+ A1                                  | 1989<br>1999         | Degrees of protection provided by enclosures (IP Code)  | EN 60529<br>+ corr. May<br>+ A1 | 1991<br>1993<br>2000 |
| IEC 60601-1-2                                      | -                    | Medical electrical equipment -<br>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 -<br>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 -<br>Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability  | EN 60601-1-6                    | -                    |

<sup>1)</sup> EN 60384-14 is superseded by EN 60384-14:2013, which is based on IEC 60384-14:2013.

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| <u>Publication</u>                          | <u>Year</u>                  | <u>Title</u>  | <u>EN/HD</u>  | <u>Year</u>          |
|---|------------------------------|---|---|----------------------|
| 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<br>1997                 | Winding wires - Test methods - Part 6: Thermal properties   | EN 60851-6 <sup>2)</sup><br>+ A1                      | 1996<br>1997         |
| IEC 60884-1                                 | -                            | Plugs and socket-outlets for household and similar purposes - Part 1: General requirements  | -   | -                    |
| IEC 60950-1 (mod) + corr. October           | 2001<br>2002                 | Information technology equipment - Safety - Part 1: General requirements  | EN 60950-1 <sup>3)</sup><br>+ corr. December<br>+ A11 | 2001<br>2007<br>2004 |
| IEC 61058-1 (mod) + corr. January + A1 + A2 | 2000<br>2009<br>2001<br>2007 | Switches for appliances - Part 1: General requirements  | EN 61058-1 <sup>4)</sup><br>+ A2                      | 2002<br>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  | -                    |

<sup>2)</sup> EN 60851-6 is superseded by EN 60851-6:2012, which is based on IEC 60851-6:2012.

<sup>3)</sup> EN 60950-1 is superseded by EN 60950-1:2006, which is based on IEC 60950-1:2005.

<sup>4)</sup> EN 61058-1 includes A1 to IEC 61058-1 (mod) + corr. January .



| <u>Publication</u> | <u>Year</u> | <u>Title</u>   | <u>EN/HD</u>                 | <u>Year</u>  |
|--------------------|-------------|--|------------------------------|--------------|
| 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<br>+ corr. November | 2006<br>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 -<br>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 -<br>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 -<br>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 -<br>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 -<br>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         |

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| <u>Publication</u> | <u>Year</u> | <u>Title</u>   | <u>EN/HD</u>   | <u>Year</u> |
|--------------------|-------------|--|----------------|-------------|
| 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        |

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## 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  |
|-----------|--|---|
| <b>I.</b> |  |   |
| <b>1.</b> | 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.<br>This shall include: | Not completely covered<br><br>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<br>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:<br>7.9.1 Paragraphs 4 and 5, intended operator  |
| <b>2.</b> | 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.<br><br>In selecting the most appropriate solutions, the manufacturer must apply the following principles in the following order:  | 1 <sup>st</sup> paragraph:<br>Covered only in respect of the following and under the condition that 2 <sup>nd</sup> paragraph (including the following 3 bullets) is taken into account:<br>8 Protection against electrical hazards from ME equipment<br>9 Protection against mechanical hazards of ME equipment and ME systems<br>15 Construction of me equipment<br><br>2 <sup>nd</sup> paragraph (including the following 3 bullets)<br>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<br>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.   |
| <b>5.</b>  | 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:<br>Instructions and information provided by the manufacturer<br>7.2.17 Marking on protective packaging<br>7.9.3.1 Technical description<br>15.3.7 Environmental influences |
| <b>6.</b>  | 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  |
| <b>II.</b> |   |  |
| <b>7</b>   | <b>Chemical, physical and biological properties</b>   | 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'.<br><br>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:<br>Toxicity:<br>11.7 Biocompatibility, the manufacturer should apply the appropriate part of the EN ISO 10993 series<br>13.1.2 Emissions, deformation of Enclosure or |