SLOVENSKI STANDARD
SIST EN 60601-1:2007/A12:2014

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Medicinska električna oprema - 1. del: Splošne zahteve za osnovno varnost in bistvene zmogljivosti

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/A12:2014**

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This amendment A12 modifies the European Standard EN 60601-1:2006; it was approved by CENELEC on 2014-09-26. 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.

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

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Foreword

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

The following dates are fixed:

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- latest date by which the national standards conflicting with the document have to be withdrawn (dow) 2015-03-26

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

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

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

In Annex ZZ of EN 60601-1:2006 (available in EN 60601-1:2006/A1:2013), ***replace*** *"Annex ZZ" by "Annex ZZA" (two occurences) and "Table ZZ.1" by "Table ZZA.1 (three occurences)".*

After Annex ZZA, ***add*** *the following new Annex:*

Annex ZZB
(informative)

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

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

General Guidance:

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

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

NOTE 2 Where a reference from a clause of this standard to the risk management process is made, the risk management process needs to be in compliance to the AIMD (Directive 90/385/EEC amended by 2007/47/EC). This means that risks have to be reduced "as far as possible", "to a minimum", "to the lowest possible level", "minimized" or "removed", according to the wording of the corresponding essential requirement.

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

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

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

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

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

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

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

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

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