SLOVENSKI STANDARD
SIST EN 60601-1-3:2008/A11:2017

01-januar-2017

Medicinska električna oprema - 1-3. del: Splošne zahteve za osnovno varnost in bistvene lastnosti - Spremljevalni standard: Zaščita pred sevanjem pri rentgenski diagnostični opremi - Dopolnilo A11

Medical electrical equipment - Part 1-3: General requirements for basic safety and essential performance - Collateral Standard: Radiation protection in diagnostic X-ray equipment

Medizinische elektrische Geräte - Teil 1-3: Allgemeine Festlegungen für die Sicherheit einschließlich der wesentlichen Leistungsmerkmale - Ergänzungsnorm: Strahlenschutz von diagnostischen Röntgengeräten

Appareils électromédicaux - Partie 1-3: Exigences générales pour la sécurité de base et les performances essentielles - Norme collatérale: Radioprotection dans les appareils à rayonnement X de diagnostic

Ta slovenski standard je istoveten z: **EN 60601-1-3:2008/A11:2016**

ICS:

11.040.50	Radiografska oprema	Radiographic equipment
13.280	Varstvo pred sevanjem	Radiation protection

SIST EN 60601-1-3:2008/A11:2017 **en**

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN 60601-1-3:2008/A11

November 2016

ICS 11.040.50; 13.280

English Version

Medical electrical equipment - Part 1-3: General requirements for basic safety and essential performance - Collateral Standard: Radiation protection in diagnostic X-ray equipment

Appareils électromédicaux - Partie 1-3: Exigences générales pour la sécurité de base et les performances essentielles - Norme collatérale: Radioprotection dans les appareils à rayonnement X de diagnostic

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This amendment A11 modifies the European Standard EN 60601-1-3:2008; it was approved by CENELEC on 2016-11-01. 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.

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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

Ref. No. EN 60601-1-3:2008/A11:2016 E

European foreword

This document (EN 60601-1-3:2008/A11:2016) 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) 2017-11-01
- latest date by which the national standards conflicting with the document have to be withdrawn (dow) 2019-11-01

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.

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.

1 Modifications to annexes

Replace *Annex ZA and Annex ZZ with the following.*

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. However, for any use of this standard “within the meaning of Annex ZZ", the user must always check that any referenced document has not been superseded and that its relevant contents can still be considered the generally acknowledged state-of-art.

When the IEC or ISO standard is referred to in the IEC text standard, this must be understood as a normative reference to the parallel EN standard, as outlined below, including the foreword and the Annexes ZZ.

NOTE 1 The way in which referenced documents are cited in normative requirements determines the extent (in whole or in part) to which they apply.

NOTE 2 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 60336		Medical electrical equipment - X-ray tube assemblies for medical use - Characteristics of focal spots	EN 60336	2005
IEC 60522	1999	Determination of the permanent filtration of X-ray tube assemblies	EN 60522	1999
IEC 60601-1	2005	Medical electrical equipment Part 1: General requirements for basic safety and essential performance	EN 60601-1	2006
A1	2012		EN 60601-1/A1	2013
			EN 60601-1/A12	2014
IEC 60788	2004	Medical electrical equipment - Glossary of defined terms		
ISO 497		Guide to the choice of series of preferred numbers and of series containing more rounded values of preferred numbers		

Annex ZZ
(informative)

Coverage of Essential Requirements of EU Directives

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 EU Directive 93/42/EEC.

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 The standard's scope is limited to the specific uses, environments, contexts, objective situations specifically indicated. It cannot provide for presumption of conformity in other conditions. Some clauses or subclauses may be not applicable due to the specific type of equipment under consideration.

NOTE 2 Only prescriptions contained in the normative parts of the text are relevant to the presumption of conformity of this standard. Informative parts may, however, support users to interpret such prescriptions correctly.

NOTE 3 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 with Directive 93/42/EEC. 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 which must be interpreted and applied in such a way as to take account of technology and practice existing at the time of design and of technical and economical considerations compatible with a high level of protection of health and safety.

NOTE 4 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 5 For all parts of this standard that a) refer in their clauses to specific national legislation possibly exempting manufacturers from the thorough application of relevant provisions of this standard or b) link the completion of a relevant process/prescription to any discretional choice/power of manufacturers, the user of the standard should check that such clauses are in compliance with Directive 93/42/EEC.

NOTE 6 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 Requirements	Coverage of EN 60601-1-3:2008 + A1:2014 + A11:2016
I.	**GENERAL REQUIREMENTS**	
1.	General Guidance notes 1 to 6 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:	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 with regard to general [1)] X-ray radiation-related aspects of the clinical condition or the safety of patients, or the safety and health of users or, where applicable, other persons (refer to Clauses 4 to 13 of this collateral 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	Covered in respect of aspects contained in Clauses 5 and 6.
	- 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 in respect of aspects contained in 5.2.4
2.	General Guidance notes 1, 2, 3, 4, 5, 6 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 under the condition that 2nd paragraph (including the following 3 bullets) is taken into account. 2nd paragraph, including the following 3 bullets, are covered for radiation protection in x-ray equipment and in subassemblies of such equipment, where radiological images of a human patient are used for diagnosis, planning or guidance of medical procedures, .in respect to aspects contained in the Clauses 5 to 13, under the condition that the manufacturer implements - EN ISO 14971 (2012) including its Annex ZA.

1) This standard is intended to provide a set of general specifications to be complemented by existing particular/device specific standards, or by other means, such as risk management.

No.	Essential Requirements	Coverage of EN 60601-1-3:2008 + A1:2014 + A11:2016
	- 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 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.	Covered in respect of aspects contained in 6.7
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.
11	**Protection against radiation**	
General Guidance notes 1, 2, 3, 4, 5, 6 shall be observed		
11.1	General	
11.1.1	Devices shall be designed and manufactured in such a way that exposure of patients, users and other persons to radiation shall be reduced as far as possible compatible with the intended purpose, whilst not restricting the application of appropriate specified levels for therapeutic and diagnostic purposes.	Covered for X-ray equipment in respect to aspects contained in Clauses 5 to 13.
11.2	Intended radiation	
11.2.1	Where devices are designed to emit hazardous levels of radiation necessary for a specific medical purpose the benefit of which is considered to outweigh the risks inherent in the emission, it must be possible for the user to control the emissions. Such devices shall be designed and manufactured to ensure reproducibility and tolerance of relevant variable parameters.	Covered for X-ray equipment with respect to aspects contained in Clause 6
11.2.2	Where devices are intended to emit potentially hazardous, visible and/or invisible radiation, they must be fitted, where practicable, with visual displays and/or audible warnings of such emissions.	Covered for X-ray equipment with respect to aspects contained in 6.4