SLOVENSKI STANDARD
SIST EN 60601-1-9:2008/A2:2020

01-november-2020

Medicinska električna oprema - 1-9. del: Splošne zahteve za osnovno varnost in bistvene lastnosti - Spremljevalni standard: Zahteve za okoljsko osveščeno snovanje - Dopolnilo A2 (IEC 60601-1-9:2007/A2:2020)

Medical electrical equipment - Part 1-9: General requirements for basic safety and essential performance - Collateral Standard: Requirements for environmentally conscious design (IEC 60601-1-9:2007/A2:2020)

Medizinische elektrische Geräte - Teil 1-9: Allgemeine Festlegungen für die Sicherheit einschließlich der wesentlichen Leistungsmerkmale - Ergänzungsnorm: Anforderungen zur Reduzierung von Umweltauswirkungen (IEC 60601-1-9:2007/A2:2020)

Appareils électromédicaux - Partie 1-9: Exigences générales pour la sécurité de base et les performances essentielles - Norme collatérale: Exigences pour une conception éco-responsable (IEC 60601-1-9:2007/A2:2020)

Ta slovenski standard je istoveten z: **EN 60601-1-9:2008/A2:2020**

ICS:

11.040.01	Medicinska oprema na splošno	Medical equipment in general
13.020.01	Okolje in varstvo okolja na splošno	Environment and environmental protection in general

SIST EN 60601-1-9:2008/A2:2020 **en**

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN 60601-1-9:2008/A2

September 2020

ICS 11.040.01; 13.020.01

English Version

Medical electrical equipment - Part 1-9: General requirements for basic safety and essential performance - Collateral Standard: Requirements for environmentally conscious design (IEC 60601-1-9:2007/A2:2020)

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Medizinische elektrische Geräte - Teil 1-9: Allgemeine Festlegungen für die Sicherheit einschließlich der wesentlichen Leistungsmerkmale - Ergänzungsnorm: Anforderungen zur Reduzierung von Umweltauswirkungen (IEC 60601-1-9:2007/A2:2020)

This amendment A2 modifies the European Standard EN 60601-1-9:2008; it was approved by CENELEC on 2020-08-26. 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.

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, Republic of North Macedonia, Romania, Serbia, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and the United Kingdom.

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

CEN-CENELEC Management Centre: Rue de la Science 23, B-1040 Brussels

European foreword

The text of document 62A/1393/FDIS, future IEC 60601-1-9/A2, 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 60601-1-9:2008/A2:2020.

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) 2021-05-26
•	latest date by which the national standards conflicting with the document have to be withdrawn	(dow) 2023-08-26

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

Endorsement notice

The text of the International Standard IEC 60601-1-9:2007/A2:2020 was approved by CENELEC as a European Standard without any modification.

Annex ZA
(normative)

Normative references to international publications with their corresponding European publications

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements 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 1 Where an International Publication has been modified by common modifications, indicated by (mod), the relevant EN/HD applies.

NOTE 2 Up-to-date information on the latest versions of the European Standards listed in this annex is available here: www.cenelec.eu.

Replace the Annex ZA of EN 60601-1-9:2008 by the following one:

Publication	Year	Title	EN/HD	Year
IEC 60601-1	2005	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance	EN 60601-1	2006
-	-		+ corrigendum Mar.	2010
+ A1	2012		+ A1	2013
-	-		+ A12	2014
+ A2	2020		+A2	—[1]

[1] Under preparation. Stage at time of publication: EN 60601-1:2006/FprA2:2020.

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INTERNATIONAL STANDARD

NORME INTERNATIONALE

AMENDMENT 2
AMENDEMENT 2

Medical electrical equipment –
Part 1-9: General requirements for basic safety and essential performance – Collateral Standard: Requirements for environmentally conscious design

Appareils électromédicaux –
Partie 1-9: Exigences générales pour la sécurité de base et les performances essentielles – Norme collatérale: Exigences pour une conception éco-responsable

INTERNATIONAL ELECTROTECHNICAL COMMISSION

COMMISSION ELECTROTECHNIQUE INTERNATIONALE

ICS 11.040.01; 13.020.01

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FOREWORD

This amendment has been prepared by subcommittee 62A: Common aspects of electrical equipment used in medical practice, of IEC technical committee 62: Electrical equipment in medical practice.

The text of this amendment is based on the following documents:

FDIS	Report on voting
62A/1393/FDIS	62A/1408/RVD

Full information on the voting for the approval of this amendment can be found in the report on voting indicated in the above table.

The committee has decided that the contents of this amendment and the base publication will remain unchanged until the stability date indicated on the IEC web site under "http://webstore.iec.ch" in the data related to the specific publication. At this date, the publication will be

- reconfirmed,
- withdrawn,
- replaced by a revised edition, or
- amended.

NOTE The attention of users of this document is drawn to the fact that equipment manufacturers and testing organizations may need a transitional period following publication of a new, amended or revised IEC or ISO publication in which to make products in accordance with the new requirements and to equip themselves for conducting new or revised tests. It is the recommendation of the committee that the content of this publication be adopted for mandatory implementation nationally not earlier than 3 years from the date of publication.

INTRODUCTION TO AMENDMENT 2

The first edition of IEC 60601-1-9 was published in 2007 and amended in 2013. Since the publication of IEC 60601-1-9:2007+A1:2013, the IEC Subcommittee (SC) 62A Secretariat has been collecting issues from a variety of sources including comments from National Committees. At the November 2015 meeting of IEC/SC 62A in Kobe, Japan, the subcommittee initiated a process to identify high-priority issues that need to be considered in an amendment and should not wait until the second edition of IEC 60601-1-9, which is presently targeted for publication sometime after 2024.

As directed in item 1 of Kobe Resolution 1, the IEC/SC 62A Chairman Advisory Group (CAG) considered the 7 issues collected by the SC/62A Secretariat for IEC 60601-1-9:2007 and determined that none met the selection criteria stated in Kobe Resolution 1.

However, an amendment is needed to update the reference to IEC 60601-1:2005+A1:2012 +A2:2020. In London in 2018, SC 62A approved the development of an administrative amendment to IEC 60601-1-9:2007+A1:2013.

Because this is an amendment to IEC 60601-1-9:2007, the style in force at the time of publication of IEC 60601-1-9 has been applied to this amendment. The specified in ISO/IEC Directives Part 2:2018 has only been applied when implementing the new style guidance would not result in additional editorial changes.

Users of this document should note that when constructing the dated references to specific elements in a standard, such as definitions, amendments are only referenced if they modified the text being cited. For example, if a reference is made to a definition that has not been modified by an amendment, then the reference to the amendment is not included in the dated reference.