SLOVENSKI STANDARD
SIST EN 60601-1-9:2008/A1:2014

01-januar-2014

Medicinska električna oprema - 1-9. del: Splošne zahteve za osnovno varnost in bistvene lastnosti - Spremljevalni standard: Zahteve za okoljsko osveščeno snovanje

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

Medizinische elektrische Geräte - Teil 1-9: Allgemeine Festlegungen für die Sicherheit einschließlich der wesentlichen Leistungsmerkmale - Ergänzungsnorm: Anforderungen zur Reduzierung von Umweltauswirkungen

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

Ta slovenski standard je istoveten z: EN 60601-1-9:2008/A1:2013

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/A1:2014 en

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN 60601-1-9/A1

November 2013

ICS 11.040; 13.020

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/A1:2013)

Appareils électromédicaux - Partie 1-9: Exigences générales pour la sécurité de base et les performances essentielles - Norme collatérale: Exigences pour une conception éco-responsable (CEI 60601-1-9:2007/A1:2013)

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/A1:2013)

This amendment A1 modifies the European Standard EN 60601-1-9:2008; it was approved by CENELEC on 2013-07-23. 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

Foreword

The text of document 62A/874/FDIS, future IEC 60601-1-9:2007/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 60601-1-9:2008/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)	2014-04-23
• latest date by which the national standards conflicting with the document have to be withdrawn	(dow)	2018-12-31

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.

Endorsement notice

The text of the International Standard IEC 60601-1-9:2007/A1:2013 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, 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.

Replacement in Annex ZA of EN 60601-1-9:2008:

Publication	Year	Title	EN/HD	Year

In the existing introductory paragraph, replace the first sentence with:

The following documents, in whole or part, are normatively referenced in this document and are indispensable for its application.

Replace the reference to IEC 60601-1:2005 with the following new reference:

IEC 60601-1 + A1	2005 2012	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance	EN 60601-1 + A1	2006 2013

IEC 60601-1-9

Edition 1.0 2013-06

INTERNATIONAL STANDARD

NORME INTERNATIONALE

AMENDMENT 1
AMENDEMENT 1

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

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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/874/FDIS	62A/881/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.

INTRODUCTION TO THE AMENDMENT

The first edition of IEC 60601-1-9 was published in 2007. This amendment is intended to update the references to IEC 60601-1:2005 to include Amendment 1:2012 and to make a few minor editorial updates.

FOREWORD

Add the following note at the end of the Foreword:

NOTE The attention of National Committees 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.

1.3 Related standards

1.3.1 IEC 60601-1

Replace the existing first dashed item with:

– "the general standard" designates IEC 60601-1 alone (IEC 60601-1:2005+A1:2012);

Replace the existing second dashed item with:

– "this collateral standard" designates IEC 60601-1-9 alone (IEC 60601-1-9:2007+A1:2013);