SLOVENSKI STANDARD
SIST EN 60601-2-3:2015/A1:2016

01-december-2016

Medicinska električna oprema - 2-3. del: Posebne zahteve za osnovno varnost in bistvene lastnosti za opremo za kratkovalovno terapijo - Predlagani horizontalni standardi - Dopolnilo A1 (IEC 60601-2-3:2012/A1:2016)

Medical electrical equipment - Part 2-3: Particular requirements for the basic safety and essential performance of short-wave therapy equipment - Proposed Horizontal Standard (IEC 60601-2-3:2012/A1:2016)

Medizinische elektrische Geräte - Teil 2-3: Besondere Festlegungen für die Sicherheit einschließlich der wesentlichen Leistungsmerkmale von Kurzwellen-Therapiegeräten (IEC 60601-2-3:2012/A1:2016)

Appareils électromédicaux - Partie 2-3: Exigences particulières pour la sécurité de base et les performances essentielles des appareils de thérapie à ondes courtes (IEC 60601-2-3:2012/A1:2016)

Ta slovenski standard je istoveten z: **EN 60601-2-3:2015/A1:2016**

ICS:

11.040.60 Terapevtska oprema Therapy equipment

SIST EN 60601-2-3:2015/A1:2016 **en**

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN 60601-2-3:2015/A1

September 2016

ICS 11.040.60

English Version

Medical electrical equipment - Part 2-3: Particular requirements for the basic safety and essential performance of short-wave therapy equipment (IEC 60601-2-3:2012/A1:2016)

Appareils électromédicaux - Partie 2-3: Exigences particulières pour la sécurité de base et les performances essentielles des appareils de thérapie à ondes courtes (IEC 60601-2-3:2012/A1:2016)

Medizinische elektrische Geräte - Teil 2-3: Besondere Festlegungen für die Sicherheit einschließlich der wesentlichen Leistungsmerkmale von Kurzwellen-Therapiegeräten (IEC 60601-2-3:2012/A1:2016)

This amendment A1 modifies the European Standard EN 60601-2-3:2015; it was approved by CENELEC on 2016-06-03. 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.

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

European foreword

The text of document 62D/1330/FDIS, future IEC 60601-2-3:2012/A1, prepared by SC 62D "Electromedical equipment", of IEC/TC 62 "Electrical equipment in medical practice" was submitted to the IEC-CENELEC parallel vote and approved by CENELEC as EN 60601-2-3:2015/A1:2016.

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) 2017-03-30
- latest date by which the national standards conflicting with the document have to be withdrawn (dow) 2019-09-30

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 93/42/EEC, see informative Annex ZZ, included in EN 60601-2-3:2015.

Endorsement notice

The text of the International Standard IEC 60601-2-3:2012/A1:2016 was approved by CENELEC as a European Standard without any modification.

IEC 60601-2-3

Edition 3.0 2016-04

INTERNATIONAL STANDARD

NORME INTERNATIONALE

AMENDMENT 1
AMENDEMENT 1

Medical electrical equipment –
Part 2-3: Particular requirements for the basic safety and essential performance of short-wave therapy equipment

Appareils électromédicaux –
Partie 2-3: Exigences particulières pour la sécurité de base et les performances essentielles des appareils de thérapie à ondes courtes

INTERNATIONAL
ELECTROTECHNICAL
COMMISSION

COMMISSION
ELECTROTECHNIQUE
INTERNATIONALE

ICS 11.040.60

ISBN 978-2-8322-3339-9

FOREWORD

This amendment has been prepared by subcommittee 62D: Electromedical equipment 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
62D/1330/FDIS	62D/1350/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 website 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.

FOREWORD

In the eleventh paragraph, replace “IEC 60601-1:2005” *by* “IEC 60601-1”.

INTRODUCTION

In the second paragraph, replace “IEC 60601-1 (third edition 2005)” *by* “IEC 60601-1”.

201.1 Scope, object and related standards

In footnote 1), replace “IEC 60601-1:2005” *by* “IEC 60601-1”.

201.3 Terms and definitions

In the first paragraph, replace “IEC 60601-1:2005” *by* “IEC 60601-1”.

201.13 HAZARDOUS SITUATIONS and fault conditions

Replace the subclause title by the following new title:

201.13 HAZARDOUS SITUATIONS and fault conditions for ME EQUIPMENT

Index of defined terms used in this particular standard

Replace all instances of "IEC 60601-1:2005" *by* "IEC 60601-1".