SLOVENSKI STANDARD
SIST EN 60601-2-2:2009/A11:2012

01-januar-2012

Medicinska električna oprema - 2-2. del: Posebne zahteve za osnovno varnost in bistvene lastnosti visokofrekvenčne kirurške opreme in visokofrekvenčnega kirurškega pribora

Medical electrical equipment - Part 2-2: Particular requirements for the basic safety and essential performance of high frequency surgical equipment and high frequency surgical accessories

Medizinische elektrische Geräte - Teil 2-2: Besondere Festlegungen für die Sicherheit einschließlich der wesentlichen Leistungsmerkmale von Hochfrequenz-Chirurgiegeräten und HF-chirurgischem Zubehör

Appareils électromédicaux - Partie 2-2: Exigences particulières pour la sécurité de base et les performances essentielles des appareils d'électrochirurgie à courant haute fréquence et des accessoires d'électrochirurgie à courant haute fréquence

Ta slovenski standard je istoveten z: **EN 60601-2-2:2009/A11:2011**

ICS:

11.040.30	Operacijski instrumenti in materiali	Surgical instruments and materials

SIST EN 60601-2-2:2009/A11:2012 **en,fr,de**

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN 60601-2-2/A11

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English version

Medical electrical equipment - Part 2-2: Particular requirements for the basic safety and essential performance of high frequency surgical equipment and high frequency surgical accessories

Appareils électromédicaux - Partie 2-2: Exigences particulières pour la sécurité de base et les performances essentielles des appareils d'électrochirurgie à courant haute fréquence et des accessoires d'électrochirurgie à courant haute fréquence

Medizinische elektrische Geräte - Teil 2-2: Besondere Festlegungen für die Sicherheit einschließlich der wesentlichen Leistungsmerkmale von Hochfrequenz-Chirurgiegeräten und HF-chirurgischem Zubehör

This amendment A11 modifies the European Standard EN 60601-2-2:2009; it was approved by CENELEC on 2011-10-01. 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

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Foreword

This document (EN 60601-2-2:2009/A11:2011) has been prepared by CLC/TC 62 “Electrical equipment in medical practice”.

The following dates are fixed:

• latest date by which this document has to be implemented at national level by publication of an identical national standard or by endorsement	(dop)	2012-10-01
• latest date by which the national standards conflicting with this document have to be withdrawn	(dow)	2014-10-01

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.

Replace *Annex ZZ of EN 60601-2-2:2009 by:*

Annex ZZ
(informative)

Coverage of Essential Requirements of EC Directives

This European Standard has been prepared under a mandate given to CENELEC by the European Commission and the European Free Trade Association and within its scope the standard covers all relevant essential requirements as given in Annex I of the EC Directive 93/42/EEC except as follows:

– Essential Requirement 6a
– Essential Requirement 7.4
– Essential Requirement 7.5 paragraph 2 & 3
– Essential Requirement 13.6 (q)

Compliance with this standard provides one means of conformity with the specified essential requirements of the Directive concerned.

WARNING: Other requirements and other EC Directives may be applicable to the products falling within the scope of this standard.