

SLOVENSKI STANDARD

SIST EN 80601-2-35:2010/A11:2012

01-januar-2012

Medicinska električna oprema - 2-35. del: Posebne zahteve za osnovno varnost in bistvene zahteve za rjuhe, blazine in posteljne vložke, namenjene za ogrevanje pri medicinski uporabi

Medical electrical equipment - Part 2-35: Particular requirements for the basic safety and essential performance of heating devices using blankets, pads and mattresses and intended for heating in medical use

Medizinische elektrische Geräte - Teil 2-35: Besondere Festlegungen für die Sicherheit einschließlich der wesentlichen Leistungsmerkmale von Decken, Matten und Matratzen zur Erwärmung von Patienten in der medizinischen Anwendung

[SIST EN 80601-2-35:2010/A11:2012](https://standards.iteh.ai/catalog/standards/sist/ac40d9ae-7ea5-4406-a438-a823069034-EN-80601-2-35:2010/A11:2012)

Appareils électromédicaux - Partie 2-35: Exigences particulières pour la sécurité de base et les performances essentielles des dispositifs de réchauffage utilisant des couvertures, des coussins ou des matelas chauffants et destinés au réchauffage des patients en usage médical

Ta slovenski standard je istoveten z: EN 80601-2-35:2009/A11:2011

ICS:

11.140

Oprema bolnišnic

Hospital equipment

SIST EN 80601-2-35:2010/A11:2012

en,fr,de

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EUROPEAN STANDARD
NORME EUROPÉENNE
EUROPÄISCHE NORM

EN 80601-2-35/A11

October 2011

ICS 11.140

English version

**Medical electrical equipment -
Part 2-35: Particular requirements for the basic safety and essential
performance of heating devices using blankets, pads and mattresses and
intended for heating in medical use**

Appareils électromédicaux -
Partie 2-35: Exigences particulières pour
la sécurité de base et les performances
essentiels des dispositifs de réchauffage
utilisant des couvertures, des coussins ou
des matelas chauffants et destinés au
réchauffage des patients en usage
médical

Medizinische elektrische Geräte -
Teil 2-35: Besondere Festlegungen für die
Sicherheit einschließlich der wesentlichen
Leistungsmerkmale von Decken, Matten
und Matratzen zur Erwärmung von
Patienten in der medizinischen
Anwendung

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This amendment A11 modifies the European Standard EN 80601-2-35:2009; 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.

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, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland and the United Kingdom.

CENELEC

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

Management Centre: Avenue Marnix 17, B - 1000 Brussels

Foreword

This document (EN 80601-2-35:2009/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.

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Replace Annex ZZ of EN 80601-2-35:2009 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 7.1
- 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.

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