



**SLOVENSKI STANDARD**  
**SIST EN 60601-1:2007/A11:2012**  
**01-januar-2012**

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**Električna medicinska oprema - 1. del: Splošne zahteve za osnovno varnost in bistvene zmogljivosti**

Medical electrical equipment - Part 1: General requirements for basic safety and essential performance

Medizinische elektrische Geräte - Teil 1: Allgemeine Festlegungen für die Sicherheit einschließlich der wesentlichen Leistungsmerkmale

Appareils électromédicaux - Partie 1: Exigences générales pour la sécurité de base et les performances essentielles

[SIST EN 60601-1:2007/A11:2012](https://standards.iteh.ai/catalog/standards/sist/dab5f5fb-1193-4663-9b27-4b44def637f6/sist-en-60601-1-2007-a11-2012)

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**Ta slovenski standard je istoveten z: EN 60601-1:2006/A11:2011**

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**ICS:**

11.040.01	Medicinska oprema na splošno	Medical equipment in general
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<b>SIST EN 60601-1:2007/A11:2012</b>	<b>en,fr,de</b>
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EUROPEAN STANDARD  
NORME EUROPÉENNE  
EUROPÄISCHE NORM

**EN 60601-1/A11**

October 2011

ICS 11.040

English version

**Medical electrical equipment -  
Part 1: General requirements for basic safety and essential performance**

Appareils électromédicaux -  
Partie 1: Exigences générales pour la  
sécurité de base et les performances  
essentielles

Medizinische elektrische Geräte -  
Teil 1: Allgemeine Festlegungen für die  
Sicherheit einschließlich der wesentlichen  
Leistungsmerkmale

**iTeh STANDARD PREVIEW**

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This amendment A11 modifies the European Standard EN 60601-1:2006; 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.

<https://standards.iteh.ai/catalog/standards/sist/dab55fb-1193-4663-9b27-546c163378/sist-en-60601-1-2007-a11-2012>  
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 60601-1:2006/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 60601-1:2006 by:**

**Annex ZZA**  
(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 the following:

- 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 Directives concerned.

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

**iTeh STANDARD PREVIEW**  
**Annex ZZB**  
(informative)  
**(standards.iteh.ai)**

**Coverage of Essential Requirements of EC Directives**

SIST EN 60601-1:2007/A11:2012

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 90/385/EEC except the following:

- Essential Requirement 5a
- Essential Requirement 7
- Essential Requirement 8 bullet 5
- Essential Requirement 10
- Essential Requirement 11
- Essential Requirement 12
- Essential Requirement 14
- Essential Requirement 15
- Essential Requirement 16

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