



**SLOVENSKI STANDARD**  
**SIST HD 395.1 S2:1998/A1:1998**  
**01-september-1998**

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**Safety of medical electrical equipment - Part 1: General requirements -  
Amendment A1 (Amendment to table XVI of HD)**

Safety of medical electrical equipment -- Part 1: General requirements

Medizinische elektrische Geräte -- Teil 1: Allgemeine Festlegungen für die Sicherheit

Securité des appareils électromédicaux -- Partie 1: Règles générales

**STANDARD PREVIEW**  
**(standards.iteh.ai)**

**Ta slovenski standard je istoveten z: HD 395.1 S2:1988/A1:1993**

<https://standards.iteh.ai/catalog/standards/sist/94d24022-a8c9-433c-8d14-9e973b095e0c/sist-hd-395-1-s2-1998-a1-1998>

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**ICS:**

11.040.01	Medicinska oprema na splošno	Medical equipment in general
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**SIST HD 395.1 S2:1998/A1:1998**                      **en**

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HARMONIZATION DOCUMENT

HD 395.1 S2/A1

DOCUMENT D'HARMONISATION

HARMONISIERUNGSDOKUMENT

January 1993

UDC 621.3::615.47 777.001.11.001.2.001.33.001.4.002.2  
614.825.001,25 003.62

Descriptors: Electromedical equipment, definitions, requirements,  
testing, construction, electrical safety, symbols

## ENGLISH VERSION

Medical electrical equipment  
Part 1: General requirements for safety

Appareils électromédicaux  
Première partie: Règles  
générales de sécurité

Medizinische elektrische  
Geräte  
Teil 1: Allgemeine Anforderungen  
an die Sicherheit

**iTeh STANDARD PREVIEW**  
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SIST HD 395.1 S2:1998/A1:1998

[https://standards.iteh.ai/catalog/standards/sist/94d24022-a8c9-433c-8d14-](https://standards.iteh.ai/catalog/standards/sist/94d24022-a8c9-433c-8d14-9473b0950c34/hd-395.1-s2-1998-a1-1998)

This amendment A1 modifies the Harmonization Document HD 395.1 S2:1988. It was approved by CENELEC on 1992-12-09. CENELEC members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for implementation of this amendment on a national level.

Up-to-date lists and bibliographical references concerning national implementation may be obtained on application to the Central Secretariat or to any CENELEC member.

This amendment exists in three official versions (English, French and German).

CENELEC members are the national electrotechnical committees of Austria, Belgium, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Luxembourg, Netherlands, Norway, Portugal, Spain, Sweden, Switzerland and United Kingdom.

## CENELEC

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

Central Secretariat: rue de Stassart 35, B-1050 Brussels

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Ref. No. HD 395.1 S2:1988/A1:1993 E

Page 2  
HD 395.1 S2:1998/A1:1993

#### FOREWORD

Following a decision taken by CENELEC Technical Committee TC 62 a draft for an amendment to HD 395.1 S2:1998 was submitted to the CENELEC Unique Acceptance Procedure (UAP) in February 1992.

The text prepared by CLC/TC 62 was approved by CENELEC as amendment A1 to HD 395.1 S2:1998 on 9 December 1992.

The following dates were fixed:

- latest date of announcement  
of the amendment at national level (doa) 1993-12-01
- latest date of publication of  
a harmonized national standard (dop) 1994-06-01
- latest date of withdrawal of  
conflicting national standards (dow) 1994-06-01

For products which have complied with HD 395.1 S2:1998 before 1994-06-01, as shown by the manufacturer or by a certification body, this previous standard may continue to apply for production until 1995-06-01.

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In the first column of table XVI replace 380 by 400.  
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