SLOVENSKI STANDARD

SIST EN 60601-1:1995

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maj 1995

Medical electrical equipment - Part 1: General requirements for safety (IEC 601-1:1988)

ICS 11.040.01

Referenčna številka
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EUROPEAN STANDARD EN 60601-1

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

ENGLISH VERSION

MEDICAL ELECTRICAL EQUIPMENT
PART 1: GENERAL REQUIREMENTS FOR SAFETY
(IEC 601-1:1988)

Appareils électromédicaux
Première partie: Règles générales de sécurité
(CEI 601-1:1988)

Medizinische elektrische Geräte
Teil 1: Allgemeine Festlegungen für die Sicherheit
(IEC 601-1:1988)

This European Standard was approved by CENELEC on 1990-06-11. CENELEC members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for giving this European Standard 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 Central Secretariat or to any CENELEC member.

This European Standard 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 Central Secretariat has the same status as the official versions.

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 Bréderode 2, B-1000 Brussels

BRIEF HISTORY

The CENELEC Questionnaire Procedure, performed for finding out whether or not IEC 601-1: 1988 could be accepted without textual changes, has shown that no CENELEC common modifications were necessary for the acceptance as a European Standard. The Reference Document was submitted to the CENELEC members for formal vote and acceptance.

The text of the International Standard IEC 601-1:1988 was approved by CENELEC on the 11th of June 1990 as a European Standard.

The following dates were fixed:

Latest date of announcement of the EN at national level	(doa)	1990-09-01
Date of latest publication of a new harmonized standard	(dop)	1991-01-01
Date of withdrawal of conflicting national standards	(dow)	1991-01-01

For products which have complied with HD 395 S2:1988 before 1991-01-01, as shown by the manufacturer or by a certification body, this previous standard may continue to apply for production until 1996-01-01.

Annex ZA (normative) lists the IEC, ISO and other publications quoted in this Standard and the corresponding CENELEC standard.

ENDORSEMENT NOTICE

The text of the International Standard IEC 601-1:1988 was approved by CENELEC as a European Standard without any modification.

ANNEX ZA (normative)

OTHER INTERNATIONAL PUBLICATIONS QUOTED IN THIS STANDARD

When the international publication has been modified by CENELEC common modifications, indicated by (mod), the relevant EN/HD applies.

IEC Publication	Date	Title	EN/HD	Date
65 (mod)	1985	Safety requirements for mains operated electronic and related apparatus for household and similar general use. Fifth edition 1985, incorporating Amendment No. 1 (1978) Amendment No. 2 (1981).	HD 195 S6	1989
68-2-2	1974	Basic environmental testing procedures. Part 2-2: Test B, Dry heat.	HD 323.2.2 S1	1988
73	1984	Colours of indicator lights and push-buttons.	HD 354 S2	1987
79	—	Electrical apparatus for explosive gas atmospheres.	—	
79-2	1983	Electrical apparatus for explosive gas atmospheres. Part 2: Electrical apparatus - type of protection "p".		
79-5:	1967	Electrical apparatus for explosive gas atmospheres. Part 5: Sand-filled apparatus.		
79-6	1968	Electrical apparatus for explosive gas atmospheres. Part 6: Oil-immersed apparatus.		
85	1984	Thermal evaluation and classification of electrical insulation.	HD 566 S1	1990
112	1979	Method for determining the comparative and the proof tracking indices of solid insulating materials under moist conditions.	HD 214 S2	1980
127	1974	Cartridge fuse-links for miniature fuses.	HD 109 S3	1983
227 (mod)	—	Polyvinyl chloride insulated cables of rated voltages up to and including 450/750 V. Amendment No. 1 (1985).	HD 21	—
241	1968	Fuses for domestic and similar purposes.	—	
245 (mod)	—	Rubber insulated cables of rated voltages up to and including 450/750V.	HD 22	—
245-4 (mod)	1980	Rubber insulating cables of rated voltages up to and including 450/750V. Part 4: Cords and flexible cords.	HD 22.4 S2	1982
252	1975	A.C. motor capacitors.	—	
309	—	Plugs, socket-outlets and couplers for industrial purposes.	HD 196	—
320 (mod)	1981	Appliance couplers for household and similar general purposes.	EN 60320-1	1987
328	1972	Switches for appliances.	—	
355-1	1970	Safety of household and similar electrical appliances. Part 1: General requirements.	—	

IEC Publication	Date	Title	EN/HD	Date
336	1982	Characteristics of focal spots in diagnostic X-ray tube assemblies for medical use.	HD 509 S1	1988
348	1978	Safety requirements for electronic measuring apparatus.	HD 401 S1	1980
364-4-41	1982	Electrical installations of buildings. Part 4: Protection for safety. Chapter 41: Protection against electric shock.	HD 384.4.41 S1	—
384-14	1981	Fixed capacitors for use in electronic equipment. Part 14: Sectional specification: Fixed capacitors for radio interference suppression. Selection of methods of test and general requirements.		
417	—	Graphical symbols for use on equipment. Index, survey and compilation of the single sheets.	HD 243	—
445	1973	Identification of apparatus terminals and general rules for a uniform system of terminal marking, using an alphanumeric notation.	HD 241 S2	1981
447	1974	Standard directions of movement for actuators which control the operation of electrical apparatus.	HD 331 S1	1977
513	1976	Basic aspects of the safety philosophy of electrical equipment used in medical practice.	—	
529	1976	Classification of degrees of protection provided by enclosures.	HD 365 S3	1985
536	1976	Classification of electrical and electronic equipment with regard to protection against electric shock.	HD 366 S1	1977
601-1	1977	Safety of medical electrical equipment. Part 1: General requirements. First edition 1977. Amendment No. 1 (1984)	HD 395 S2	1988
664	1980	Insulation co-ordination within low-voltage systems including clearances and creepage distances for equipment.	—	
695	—	Fire hazard testing.	HD 444	—
707	1981	Methods of test for the determination of the flammability of solid electrical insulating materials when exposed to an igniting source.	HD 441 S1	1983
742 (mod)	1983	Isolating transformers and safety isolating transformers: Requirements.	EN 60742	1989
878	1988	Graphical symbols for electrical equipment in medical practice.		

ISO Publication		
ISO 32	1977	Gas cylinders for medical use — Marking for identification of content.
ISO 407	1983	Small medical gas cylinders — Yoke-type vale connections.
ISO 471	1983	Rubber — Standard temperatures, humidities and times for the conditioning and testing of test pieces.
ISO 780	1985	Packaging — Pictorial marking for handling of goods.

ISO Publication	Page	Title
ISO 1853	1975	Conducting and antistatic rubbers — Measurement of resistivity.
ISO 2878	1987	Rubber, vulcanized — Antistatic and conductive products — Determination of electrical resistance.
ISO 2882	1979	Rubber, vulcanized — Antistatic and conductive products for hospital use — Electrical resistance limits.
ISO 8185	1988	Humidifiers for medical use — Safety requirements.

CLC/TC62

CENELEC

19-08-1994

Corrigendum to EN 60601-1:1990

English version

Foreword

Replace the "date of withdrawal of conflicting national standards" and the subsequent paragraph by:

Date of withdrawal of conflicting national standards (dow) -

This European Standard replaces HD 395.1 S2:1988. However, HD 395.1 S2:1988 remains valid until all parts 2 which are used in conjunction with it have been withdrawn. No date of withdrawal of conflicting standards (dow) has therefore been fixed.

NOTE: The General Standard applies, as far as is reasonable, to medical equipment not covered by a Particular Standard, in which case HD 395.1 S2:1988 is not to be used after 1994-06-01.

Add the following annex:

Annex ZC (informative)

A-deviations

A-deviation: National deviation due to regulations, the alteration of which is for the time being outside the competence of the CENELEC member.

6.6 **Austria** (Dampfkesselverordnung, BGBl. 510/1986)

The identification of medical gas cylinders and connections are regulated according to the Dampfkesselverordnung, BGBl. 510/1986 in compliance with the Austrian standards ÖNORM K 3010, M 7375, M 7387 and M 7886, which are not in conformity with ISO recommendation ISO/R32.

6.8.1 **Finland** (Resolution of the Ministry of Trade and Industry on Electrical Safety Regulations, 205/74)

Warnings and instructions for use, required to be on the outside of the equipment, shall be in Finnish and Swedish.

56.3a **Austria** (Dampfkesselverordnung, BGBl. 510/1986)

The identification of medical gas cylinders and connections are regulated according to the Dampfkesselverordnung, BGBl. 510/1986 in compliance with the Austrian standards ÖNORM K 3010, M 7375, M 7387 and M 7886, which are not in conformity with ISO recommendation ISO/R407.

57.10 a) **Finland** (Resolution of the Ministry of Trade and Industry on Electrical Safety Regulations, 205/74)

Addition:

- Distance through solid insulation between metal parts for *U* higher than 60 V: separated by supplementary insulation 0,4 mm or separated by reinforced insulation 0,4 mm.

July 1994

NORME INTERNATIONALE
INTERNATIONAL STANDARD

205

CEI
IEC
601-1

Deuxième édition
Second edition
1988

Commission Electrotechnique Internationale
International Electrotechnical Commission
Международная Электротехническая Комиссия

Appareils électromédicaux

Première partie: Règles générales de sécurité

Medical electrical equipment

Part 1: General requirements for safety

Publication
601-1: 1988

CONTENTS

Clause Page

INTERNATIONAL ELECTROTECHNICAL COMMISSION

MEDICAL ELECTRICAL EQUIPMENT

Part 1: General requirements for safety

FOREWORD

1) The formal decisions or agreements of the IEC on technical matters, prepared by Technical Committees on which all the National Committees having a special interest therein are represented, express, as nearly as possible, an international consensus of opinion on the subjects dealt with.

2) They have the form of recommendations for international use and they are accepted by the National Committees in that sense.

3) In order to promote international unification, the IEC expresses the wish that all National Committees should adopt the text of the IEC recommendation for their national rules in so far as national conditions will permit. Any divergence between the IEC recommendation and the corresponding national rules should, as far as possible, be clearly indicated in the latter.

PREFACE

This Standard has been prepared by Sub-Committee 62A: Common aspects of electrical equipment used in medical practice, of IEC Technical Committee No. 62: Electrical equipment in medical practice.

It forms the second edition of IEC Publication 601-1 (1977), entitled "Safety of medical electrical equipment, Part 1: General requirements".

The text of this Standard is based on the following documents:

Six Months' Rule	Report on Voting	Two Months' Procedure	Report on Voting
62A(CO)24	62A(CO)25	62A(CO)27	62A(CO)33

Full information on the voting for the approval of this Standard can be found in the Voting Reports indicated in the above table.

The list of IEC, ISO and other publications quoted in this Standard will be found in Appendix L.

In this Standard, the following print types are used:

Requirements, compliance with which can be tested and definitions: in roman type.

Explanations, advice, introductions, general statements, exceptions and references: in smaller type.

Test specifications: in italic type.

TERMS USED THROUGHOUT THIS STANDARD WHICH HAVE BEEN DEFINED IN CLAUSE 2 AND ALSO GIVEN IN THE INDEX: SMALL CAPITALS.

* Rationale (Appendix A).