

## **Elektrilised meditsiiniseadmed. Osa 1: Üldised ohutusnõuded**

Medical electrical equipment. Part 1: General  
requirements for safety

## EESTI STANDARDI EESSÕNA

## NATIONAL FOREWORD

<p>Käesolev Eesti standard EVS-EN 60601-1:2000 sisaldab Euroopa standardi EN 60601-1:1990+A1,2,11-13:1996 ingliskeelset teksti.</p> <p>Käesolev dokument on jõustatud 16.03.2000 ja selle kohta on avaldatud teade Eesti standardiorganisatsiooni ametlikus väljaandes.</p> <p>Standard on kättesaadav Eesti standardiorganisatsioonist.</p>	<p>This Estonian standard EVS-EN 60601-1:2000 consists of the English text of the European standard EN 60601-1:1990+A1,2,11-13:1996.</p> <p>This document is endorsed on 16.03.2000 with the notification being published in the official publication of the Estonian national standardisation organisation.</p> <p>The standard is available from Estonian standardisation organisation.</p>
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ICS 11.040.01

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UDC 615.84:614.8

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  
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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,  
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## 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.

<u>IEC</u> <u>Publication</u>	<u>Date</u>	<u>Title</u>	<u>EN/HD</u>	<u>Date</u>
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

<u>Publication</u>	<u>Date</u>	<u>Title</u>	<u>EN/HD</u>	<u>Date</u>
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 valve 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.