



National Standards Authority of Ireland

IRISH STANDARD

I.S. EN 60601-1 : 1991

ICS 11.040

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

*This Irish Standard was
published under the
authority of the National
Standards Authority of
Ireland
and comes into effect on:
June 23, 1992*

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Údarás um Chaighdeán Náisiúnta na hÉireann

EUROPEAN STANDARD
NORME EUROPÉENNE
EUROPÄISCHE NORM

EN 60601-1

August 1990

+ A1 + A2
May 1993 June 1995
+ A11 + A13
May 1993 January 1996
+ A12
May 1993

UDC 615.84 : 614.8

Incorporates corrigendum July 1994

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

English version

Medical electrical equipment

Part 1: General requirements for safety

(Includes amendments A1 : 1993, A11 : 1993, A12 : 1993, A2 : 1995 and A13 : 1996)

(IEC 601-1 : 1988 + A1 : 1991 + A2 : 1995 + corrigendum 1995, mod.)

Appareils électromédicaux Première partie:
Règles générales de sécurité
(Inclut les amendements A1 : 1993, A11 : 1993,
A12 : 1993, A2 : 1995 et A13 : 1996)
(CEI 601-1 : 1988 + A1 : 1991 + A2 : 1995 +
corrigendum 1995, modifié)

Medizinische elektrische Geräte
Teil 1: Allgemeine Festlegungen für die Sicherheit
(Enthält Änderungen A1 : 1993, A11 : 1993,
A12 : 1993, A2 : 1995 und A13 : 1996)
(IEC 601-1 : 1988 + A1 : 1991 + A2 : 1995 +
corrigendum 1995, modifiziert)

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 de Stassart 35, B-1050 Brussels

Brief history of EN 60601-1

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) -

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.

Foreword of amendment A1

At the request of the CENELEC Technical Committee TC 62: Electrical equipment in medical practice, amendment 1 : 1991 to the International Standard IEC 601-1 : 1988 was submitted to the CENELEC Unique Acceptance Procedure (UAP) in February 1992 for acceptance as a European Standard.

The text of the amendment to the International Standard was approved by CENELEC as amendment A1 to EN 60601-1 on 9 December 1992.

The following dates were fixed:

- latest date of publication of an identical national standard (dop) 1994-06-01

Foreword of amendment A11

Following a decision by CENELEC Technical Committee TC 62: Electrical equipment in medical practice, a draft for an amendment to EN 60601-1 : 1990 was submitted to the CENELEC Unique Acceptance Procedure (UAP) in February 1992.

The aim of this draft was to split up the original annex ZA (normative) into a new annex ZA (normative) and an annex ZB (informative).

The text as prepared by CLC/TC 62 was approved by CENELEC as amendment A11 to EN 60601-1 on 9 December 1992.

The following dates were fixed:

- latest date of publication of an identical national standard (dop) 1994-06-01

Foreword of amendment A12

Following a decision taken by CENELEC Technical Committee TC 62: Electrical equipment in medical practice, a draft for an amendment to EN 60601-1 : 1990 was submitted to the CENELEC Unique Acceptance Procedure (UAP) in February 1992.

The test prepared by CLC/TC 62 was approved by CENELEC as amendment A12 to EN 60601-1 on 9 December 1992.

The following dates were fixed:

- latest date of publication of an identical national standard (dop) 1994-06-01

Foreword of amendment A2

The text of document 62A(CO)45, future amendment 2 to IEC 601-1 : 1988, prepared by SC 62A, Common aspects of electrical equipment used in medical practice, of IEC TC 62, Electrical equipment in medical practice, was submitted to the IEC-CENELEC parallel vote and was approved by CENELEC as amendment A2 to EN 60601-1 : 1990 on 1995-03-06.

This European Standard supersedes EN 60601-1 : 1990/A11 : 1993.

The following date was fixed:

- latest date by which the amendment has to be implemented at national level by publication of an identical national standard or by endorsement (dop) 1996-03-01

Foreword of amendment A13

This amendment was prepared by the Technical Committee CENELEC TC 62, Electrical equipment in medical practice.

The text of the draft was submitted to the formal vote and was approved by CENELEC as amendment A13 to EN 60601-1 : 1990 on 1995-07-04.

The following dates were fixed:

- latest date by which the amendment has to be implemented at national level by publication of an identical national standard or by endorsement (dop) 1996-07-01
- latest date by which the national standards conflicting with the amendment have to be withdrawn (dow) 1996-07-01

Annex ZD (normative) lists the special national conditions causing a deviation from this amendment for a transitional period ending at the latest at 2006-07-01.

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