STANDARDISERINGEN I SVERIGE
SWEDISH STANDARDS INSTITUTION

SVENSK STANDARD SS-EN 60601-2-18

Handläggande organ	Fastställd	Utgåva	Sida	Ingår i
Svenska Elektriska Kommissionen, SEK	1997-02-28	1	1 (1+25)	SEK Övers kt 62
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Elektrisk utrustning för medicinskt bruk - Säkerhet - Del 2: Särskilda fordringar på utrustning för endoskopi

Medical electrical equipment - Part 2: Particular requirements for the safety of endoscopic equipment

Som svensk standard g ller europastandarden EN 60601-2-18:1996. Den svenska standarden inneh ller den officiella engelska spr kversionen av EN 60601-2-18:1996.

Nationellt f rord

Europastandarden EN 60601-2-18: 1996

best r av:

- **europastandardens ikrafts ttningsdokument,** utarbetat inom CENELEC

- **IEC 601-2-18, Second edition, 1996 - Medical electrical equipment - Part 2: Particular requirements for the safety of endoscopic equipment**

utarbetad inom International Electrotechnical Commission, IEC.

Standarden skall anv ndas tillsammans med SS-EN 60601-1, Elektromedicinsk utrustning - S kerhet - De1 1: Allm nna fordringar, och dess separat utgivna till gg.

Till SS-EN 60601-1 utges en serie till ggsstandarder som anger allm nna fordringar p s kerhet som r till mpliga p

- en grupp av elektrisk utrustning f r medicinskt bruk, t ex radiologisk utrustning
- s rskilda egenskaper hos all elektrisk utrustning f r medicinskt bruk, ej s rskilt behandlade i SS-EN 60601-1, t ex elektromagnetisk kompatibilitet.

ICS 11.040.50

Standarder kan beställas hos SIS som även lämnar allmänna upplysningar om svensk och utländsk standard.
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Prisgrupp R

Tryckt i april 1997

EUROPEAN STANDARD
NORME EUROPÉENNE
EUROPÄISCHE NORM

EN 60601-2-18

September 1996

ICS 11.040.50

Descriptors: **Medical electrical equipment, endoscopy, safety requirements, protection against electric shock, protection against mechanical hazard, radiation protection, fire protection, environmental conditions**

English version

Medical electrical equipment
Part 2: Particular requirements for the safety of endoscopic equipment
(EC 601-2-18:1996)

Appareils électromédicaux
Partie 2: Règles particulières de sécurité pour appareils d'endoscopie
(CEI 601-2-18: 1996)

Medizinische elektrische Geräte
Teil 2: Besondere Festlegungen für die Sicherheit von endoskopischen Geräten
(IEC 601-2-18: 1996)

This European Standard was approved by CENELEC on 1996-07-02. CENELEC members are bound to comply with the CEN/ENELEC 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.

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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

Ref. No. EN 60601-2-18:1996 E

Foreword

The text of document 62D/191/FDIS, future edition 2 of IEC 601-2-18, prepared by SC 62D, Electromedical equipment, of IEC TC 62, Electrical equipment in medical practice, was submitted to the IEC-CENELEC parallel vote and was approved by CENELEC as EN 60601-2-18 on 1996-07-02.

The following dates were fixed:

- latest date by which the EN has to be implemented at national level by publication of an identical national standard or by endorsement (dop) 1997-05-01
- latest date by which the national standards conflicting with the EN have to be withdrawn (dow) 1997-05-01

Annexes designated “normative” are part of the body of the standard.
Annexes designated “informative” are given for information only.
In this standard, annex ZA is normative and annex AA is informative.
Annex ZA has been added by CENEEEC.

Endorsement notice

The text of the International Standard IEC 601-2-18:1996 was approved by CENELEC as a European Standard without any modification.

Annex ZA (normative)

Normative references to international publications with their corresponding European publications

This European Standard incorporates by dated or undated reference, provisions from other publications. These normative references are cited at the appropriate places in the text and the publications are listed hereafter. For dated references, subsequent amendments to or revisions of any of these publications apply to this European Standard only when incorporated in it by amendment or revision. For undated references the latest edition of the publication referred to applies (including amendments).

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

Publication	Year	Title	EN/HD	Year
Addition to annex ZA of EN 60601-1:1990/A2:1995:				
IEC 417	1973	Graphical symbols for use on equipment Index, survey and compilation of the single sheets	HD 243 S12[1)]	1995
IEC 601-1	1988	Medical electrical equipment Part 1: General requirements for safety	EN 60601-1 + corr. July	1990 1994
A1	1991		A1 + corr. July	1993 1994
A2	1995		A2 A13	1995 1996
IEC 601-1-1	1992	1. Collateral standard: Safety requirements for medical electrical systems	EN 60601-1 -1	1993
A1	1995		A1	1996
IEC 601-2-2	1991	Part 2: Particular requirements for the safety of high frequency surgical equipment	EN 60601-2-2	1993
IEC 601-2-37	199X[2)]	Part 2: Particular requirements for safety of ultrasonic diagnostic and monitoring equipment		-
IEC 664-1 (mod)	1992	Insulation coordination for equipment within low-voltage systems Part 1: Principles, requirements and tests	HD 625.1 S1	1996
CISPR 11 (mod)	1990	Limits and methods of measurement of radio disturbance characteristics of industrial, scientific and medical (ISM) radio-frequency equipment	EN 55011	1991

1) HD 243 S12 includes supplements A:1974 to M:1994 to IEC 417.

2) At present at the stage of Committee Draft ref 62B/290/CD.

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Part 2: Particular requirements for the safety of endoscopic equipment

SECTION ONE - GENERAL

The clauses and subclauses of this section of the General Standard apply except as follows:

1 Scope and object

This clause of the General Standard applies, except as follows:

1.1 *Scope*

Addition:

This Particular Standard specifies requirements for the safety of ENDOSCOPIC EQUIPMENT and its INTERCONNECTION CONDITIONS with ENDOSCOPICALLY-USED ACCESSORIES.

NOTE - As the General Standard does not give requirements for the safety of APPLIED PARTS of different MEDICAL ELECTRICAL EQUIPMENT when used together, this standard gives requirements for specific INTERCONNECTION CONDITIONS commonly encountered during the use of ENDOSCOPES.

1.2 Object

Replacement:

The object of this Particular Standard to establish particular requirements for the safety of ENDOSCOPIC EQUIPMENT and enable parts of ENDOSCOPIC EQUIPMENT to be tested together or individually.

1.3 Particular Standards

Addition:

This Particular Standard amends and supplements a set of IEC publications, hereinafter referred to as “General Standard”, consisting of IEC 601-1: 1988, *Medical electrical equipment - Part 1: General requirements for* safety, amendment 1, amendment *2,* IEC 601-1-1: 1992, *Medical electrical equipment - Part 1: General requirements for safety, 1. Collateral Standard: Safety requirements for medical electrical systems,* amendment 1, and IEC *601-1-2:* 1993, *Medical electrical equipment - Part 1: General requirements for safety, 2. Collateral standard: Electromagnetic compatibility - Requirements and tests.*

For brevity, IEC 601-1 is referred to in this Particular Standard either as the “General Standard” or as the “General Requirement(s)“, and IEC 601-1-1 and IEC 601-1-2 as the “Collateral Standards”.

The term “this Standard” covers this Particular Standard, used together with the General Standard and Collateral Standards.

The numbering of sections, clauses and subclauses of this Particular Standard corresponds with that of the General Standard. The changes to the text of the General Standard are specified by the use of the following words:

“Replacement” means that the clause or subclause of the General Standard is replaced completely by the text of this Particular Standard.

“Addition” means that the text of this Particular Standard is additional to the requirements of the General Standard.

“Amendment” means that the clause of subclause of the General Standard is amended as indicated by the text of this Particular Standard.

Subclauses or figures which are additional to those of the General Standard are numbered starting from 101, additional annexes are lettered AA, BB, etc., and additional items *aa), bb;),* etc.

Clauses and subclauses to which there is a rationale are marked with an asterisk *. These rationales can be found in an informative annex AA. Annex AA is not part of this Particular Standard and only gives additional information; it can never be the subject of testing.

Where there is no corresponding section, clause or subclause in this Particular Standard, the section, clause or subclause of the General Standard or Collateral Standard applies without modification.

Where it is intended that any part of the General Standard or Collateral Standards, although possibly irrelevant, is not to be applied, a statement to that effect is given in this Particular Standard.

A requirement of this Particular Standard replacing or modifying requirements of the General Standard or Collateral Standards takes precedence over the corresponding General Requirement(s).