SLOVENSKI STANDARD
SIST EN 80601-2-58:2009

01-april-2009

Medicinska elektriļ na oprema - 2-58. del: Posebne zahteve za osnovno varnost in bistvene lastnosti naprav za odstranjevanje leļ in naprav za vitrektomijo pri oļ esni kirurgiji (IEC 80601-2-58:2008)

Medical electrical equipment - Part 2-58: Particular requirements for basic safety and essential performance of lens removal devices and vitrectomy devices for ophthalmic surgery (IEC 80601-2-58:2008)

Medizinische elektrische Geräte - Teil 2-58: Besondere Festlegungen für die Sicherheit einschließlich der wesentlichen Leistungsmerkmale für Geräte zur Linsenentfernung und Geräte zur Glaskörperentfernung in der Augenchirurgie (IEC 80601-2-58:2008)

Appareils électromédicaux - Partie 2-58: Exigences particulières pour la sécurité de base et les performances essentielles des dispositifs de retrait du cristallin et des dispositifs de vitrectomie pour la chirurgie ophtalmique (CEI 80601-2-58:2008)

Ta slovenski standard je istoveten z: **EN 80601-2-58:2009**

ICS:

11.040.70	Oftalmološka oprema	Ophthalmic equipment

SIST EN 80601-2-58:2009 **en,fr**

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN 80601-2-58

February 2009

ICS 11.040.70

English version

Medical electrical equipment - Part 2-58: Particular requirements for the basic safety and essential performance of lens removal devices and vitrectomy devices for ophthalmic surgery

(IEC 80601-2-58:2008)

Appareils électromédicaux - Partie 2-58: Exigences particulières pour la sécurité de base et les performances essentielles des dispositifs de retrait du cristallin et des dispositifs de vitrectomie pour la chirurgie ophtalmique (CEI 80601-2-58:2008)

Medizinische elektrische Geräte - Teil 2-58: Besondere Festlegungen für die Sicherheit einschließlich der wesentlichen Leistungsmerkmale für Geräte zur Linsenentfernung und Geräte zur Glaskörperentfernung in der Augenchirurgie (IEC 80601-2-58:2008)

This European Standard was approved by CENELEC on 2009-02-01. 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, Bulgaria, Cyprus, the Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, the Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland and the United Kingdom.

CENELEC

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

Central Secretariat: avenue Marnix 17, B - 1000 Brussels

Ref. No. EN 80601-2-58:2009 E

Foreword

The text of document 62D/701/FDIS, future edition 1 of IEC 80601-2-58, prepared by SC 62D, Electromedical equipment, of IEC TC 62, Electrical equipment in medical practice, and SC 7, Ophthalmic optics and instruments, of ISO TC 172, Optics and photonics, was submitted to the IEC-CENELEC parallel vote and was approved by CENELEC as EN 80601-2-58 on 2009-02-01.

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)	2009-11-01
– latest date by which the national standards conflicting with the EN have to be withdrawn	(dow)	2012-02-01

This European Standard has been prepared under a mandate given to CENELEC by the European Commission and the European Free Trade Association and covers essential requirements of EC Directive MDD (93/42/EEC). See Annex ZZ.

In this standard, the following print types are used:

– Requirements and definitions: roman type.

– *Test specifications: italic type.*

– Informative material appearing outside of tables, such as notes, examples and references: in smaller type. Normative text of tables is also in a smaller type.

– TERMS DEFINED IN CLAUSE 3 OF THE GENERAL STANDARD, IN THIS PARTICULAR STANDARD OR AS NOTED: SMALL CAPITALS.

In referring to the structure of this standard, the term

– “clause” means one of the seventeen numbered divisions within the table of contents, inclusive of all subdivisions (e.g. Clause 7 includes subclauses 7.1, 7.2, etc.);

– “subclause” means a numbered subdivision of a clause (e.g. 7.1, 7.2 and 7.2.1 are all subclauses of Clause 7).

References to clauses within this standard are preceded by the term “Clause” followed by the clause number. References to subclauses within this particular standard are by number only.

In this standard, the conjunctive “or” is used as an “inclusive or” so a statement is true if any combination of the conditions is true.

The verbal forms used in this standard conform to usage described in Annex H of the ISO/IEC Directives, Part 2. For the purposes of this standard, the auxiliary verb:

− “shall” means that compliance with a requirement or a test is mandatory for compliance with this standard;

− “should” means that compliance with a requirement or a test is recommended but is not mandatory for compliance with this standard;

− “may” is used to describe a permissible way to achieve compliance with a requirement or test.

An asterisk (*) as the first character of a title or at the beginning of a paragraph or table title indicates that there is guidance or rationale related to that item in Annex AA.

Annexes ZA and ZZ have been added by CENELEC.

Endorsement notice

The text of the International Standard IEC 80601-2-58:2008 was approved by CENELEC as a European Standard without any modification.

In the official version, for Bibliography, the following notes have to be added for the standards indicated:

IEC 60065	NOTE	Harmonized as EN 60065:2002 (modified).
IEC 60825-1	NOTE	Harmonized as EN 60825-1:2007 (not modified).
IEC 60950-1	NOTE	Harmonized as EN 60950-1:2006 (modified).
ISO 15004-2	NOTE	Harmonized as EN ISO 15004-2:2007 (not modified).

Annex ZA
(normative)

Normative references to international publications with their corresponding European publications

The following referenced documents are indispensable for the application of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

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
IEC 60601-1-2 (mod)	2007	Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests	EN 60601-1-2	2007
IEC 60601-2-2	200X	Medical electrical equipment - Part 2-2: Particular requirements for basic safety and essential performance of high frequency surgical equipment and high frequency surgical accessories	EN 60601-2-2	200X
IEC 60601-2-22	-[1)]	Medical electrical equipment - Part 2-22: Particular requirements for basic safety and essential performance of surgical, cosmetic, therapeutic and diagnostic laser equipment	-	-
IEC 61847	1998	Ultrasonics - Surgical systems - Measurement and declaration of the basic output characteristics	EN 61847	1998
ISO 11607-1	2006	Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems and packaging systems	EN ISO 11607-1	2006
ISO 11607-2	2006	Packaging for terminally sterilized medical devices - Part 2: Validation requirements for forming, sealing and assembly processes	EN ISO 11607-2	2006
ISO 15752	2000	Ophthalmic instruments - Endoilluminators - Fundamental requirements and test methods for optical radiation safety	-	-
ISO 17664	2004	Sterilization of medical devices - Information to be provided by the manufacturer for the processing of resterilizable medical devices	EN ISO 17664	2004

[1)] Undated reference.

Annex ZZ
(informative)

Coverage of Essential Requirements of EC Directives

This European Standard has been prepared under a mandate given to CENELEC by the European Commission and the European Free Trade Association and within its scope the standard covers all relevant essential requirements as given in Annex I of the EC Directive 93/42/EEC.

Compliance with this standard provides one means of conformity with the specified essential requirements of the Directive concerned.

WARNING: Other requirements and other EC Directives may be applicable to the products falling within the scope of this standard.

IEC 80601-2-58

Edition 1.0 2008-10

INTERNATIONAL STANDARD

NORME INTERNATIONALE

Medical electrical equipment –
Part 2-58: Particular requirements for the basic safety and essential performance of lens removal devices and vitrectomy devices for ophthalmic surgery

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CONTENTS

INTERNATIONAL ELECTROTECHNICAL COMMISSION

MEDICAL ELECTRICAL EQUIPMENT –

Part 2-58: Particular requirements for the basic safety and essential performance of lens removal devices and vitrectomy devices for ophthalmic surgery

FOREWORD

1) The International Electrotechnical Commission (IEC) is a worldwide organization for standardization comprising all national electrotechnical committees (IEC National Committees). The object of IEC is to promote international co-operation on all questions concerning standardization in the electrical and electronic fields. To this end and in addition to other activities, IEC publishes International Standards, Technical Specifications, Technical Reports, and Guides (hereafter referred to as "IEC Publication(s)"). Their preparation is entrusted to technical committees; any IEC National Committee interested in the subject dealt with may participate in this preparatory work. International, governmental and non-governmental organizations liaising with the IEC also participate in this preparation. IEC collaborates closely with the International Organization for Standardization (ISO) in accordance with conditions determined by agreement between the two organizations.
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8) Attention is drawn to the Normative references cited in this publication. Use of the referenced publications is indispensable for the correct application of this publication.
9) Attention is drawn to the possibility that some of the elements of this IEC Publication may be the subject of patent rights. IEC shall not be held responsible for identifying any or all such patent rights.

International standard IEC 80601-2-58 has been prepared by IEC subcommittee 62D: Electromedical equipment, of IEC technical committee 62: Electrical equipment in medical practice, and ISO subcommittee SC 7: Ophthalmic optics and instruments of ISO technical committee 172: Optics and photonics.

It is published as a double logo standard.

The text of this particular standard is based on the following documents:

FDIS	Report on voting
62D/701/FDIS	62D/723/RVD

Full information on the voting for the approval of this particular standard can be found in the report on voting indicated in the above table. In ISO, the standard has been approved by 14 P-members out of 15 having cast a vote.

This publication has been drafted in accordance with the ISO/IEC Directives, Part 2.

In this standard, the following print types are used:

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An asterisk (*) as the first character of a title or at the beginning of a paragraph or table title indicates that there is guidance or rationale related to that item in Annex AA.

A list of all parts of the IEC 60601 series, published under the general title *Medical electrical equipment,* can be found on the IEC website.

The committee has decided that the contents of this particular standard will remain unchanged until the maintenance result date indicated on the IEC web site under "http://webstore.iec.ch" in the data related to the specific publication. At this date, the publication will be

- reconfirmed;
- withdrawn;
- replaced by a revised edition, or
- amended