SLOVENSKI STANDARD
kSIST FprEN ISO 80601-2-56:2012

01-maj-2012

Elektromedicinska oprema - 2-56. del: Posebne zahteve za osnovno varnost in bistvene lastnosti kliničnih termometrov za merjenje telesne temperature (ISO 80601-2-56:2009)

Medical electrical equipment - Part 2-56: Particular requirements for basic safety and essential performance of clinical thermometers for body temperature measurement (ISO 80601-2-56:2009)

Medizinische elektrische Geräte - Teil 2-56: Besondere Festlegungen für die Sicherheit einschließlich der wesentlichen Leistungsmerkmale von medizinischen Thermometern zum Messen der Körpertemperatur (ISO 80601-2-56:2009)

Appareils électromédicaux - Partie 2-56: Exigences particulières relatives à la sécurité fondamentale et aux performances essentielles des thermomètres médicaux pour mesurer la température de corps (ISO 80601-2-56:2009)

Ta slovenski standard je istoveten z: **FprEN ISO 80601-2-56**

ICS:

11.040.55	Diagnostična oprema	Diagnostic equipment

kSIST FprEN ISO 80601-2-56:2012 **en**

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

FINAL DRAFT
FprEN ISO 80601-2-56

March 2012

ICS 11.040.55

Will supersede EN 12470-3:2000+A1:2009, EN 12470-4:2000+A1:2009, EN 12470-5:2003

English Version

Medical electrical equipment - Part 2-56: Particular requirements for basic safety and essential performance of clinical thermometers for body temperature measurement (ISO 80601-2-56:2009)

Appareils électromédicaux - Partie 2-56: Exigences particulières relatives à la sécurité fondamentale et aux performances essentielles des thermomètres médicaux pour mesurer la température de corps (ISO 80601-2-56:2009)

Medizinische elektrische Geräte - Teil 2-56: Besondere Festlegungen für die Sicherheit einschließlich der wesentlichen Leistungsmerkmale von medizinischen Thermometern zum Messen der Körpertemperatur (ISO 80601-2-56:2009)

This draft European Standard is submitted to CEN members for unique acceptance procedure. It has been drawn up by the Technical Committee CEN/TC 205.

If this draft becomes a European Standard, CEN 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.

This draft European Standard was established by CEN in three official versions (English, French, German). A version in any other language made by translation under the responsibility of a CEN member into its own language and notified to the CEN-CENELEC Management Centre has the same status as the official versions.

CEN members are the national standards bodies of Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and United Kingdom.

Recipients of this draft are invited to submit, with their comments, notification of any relevant patent rights of which they are aware and to provide supporting documentation.

Warning : This document is not a European Standard. It is distributed for review and comments. It is subject to change without notice and shall not be referred to as a European Standard.

EUROPEAN COMMITTEE FOR STANDARDIZATION
COMITÉ EUROPÉEN DE NORMALISATION
EUROPÄISCHES KOMITEE FÜR NORMUNG

Management Centre: Avenue Marnix 17, B-1000 Brussels

Contents

Page

Foreword

The text of ISO 80601-2-56:2009 has been jointly prepared by Technical Committee ISO/TC 121 “Anaesthetic and respiratory equipment” of the International Organization for Standardization (ISO) and Sub-Committee IEC/SC 62D “Electromedical equipment” of the International Electrotechnical Commission (IEC) and has been taken over as FprEN ISO 80601-2-56:2012 by Technical Committee CEN/TC 205 “Non-active medical devices” the secretariat of which is held by DIN..

This document is currently submitted to the Unique Acceptance Procedure.

This document will supersede EN 12470-3:2000+A1:2009, EN 12470-4:2000+A1:2009, EN 12470-5:2003,.

This document has been prepared under a mandate given to CEN by the European Commission and the European Free Trade Association, and supports essential requirements of EU Directive(s).

For relationship with EU Directive(s), see informative Annex ZA, which is an integral part of this document.

Endorsement notice

The text of ISO 80601-2-56:2009 has been approved by CEN as a FprEN ISO 80601-2-56:2012 without any modification.

Annex ZA
(informative)

Relationship between this European Standard and the Essential Requirements of EU Directive 93/42/EEC on medical devices

This European Standard has been prepared under a mandate given to CEN by the European Commission and the European Free Trade Association to provide a means of conforming to Essential Requirements of the New Approach Directive 93/42/EEC on medical devices.

Once this standard is cited in the Official Journal of the European Union under that Directive and has been implemented as a national standard in at least one Member State, compliance with the clauses of this standard given in table ZA.1 confers, within the limits of the scope of this standard, a presumption of conformity with the corresponding Essential Requirements of that Directive and associated EFTA regulations.

Table ZA.1 — Correspondence between this European Standard and Directive 93/42/EEC on medical devices

Clause(s)/sub-clause(s) of this International standard	Essential requirements (ERs) of EU Directive 93/42/EEC	Qualifying remarks/Notes
201.11	7.2	Only the parts of ER 7.2 relating to safety in use for the patient are addressed.
201.11	7.3	Only the part of the first sentence relating to design is addressed.
201.7.9.2.14.101	7.5	Only the third paragraph of ER 7.5 is addressed.
201.11, 201.103	7.6	
201.11	8.1	The part of ER 8.1 relating to easy handling is not addressed.
201.11	8.4	Validated processes for sterilization are required via the normative references to ISO 11134, ISO 11135, ISO 11137.
201.7.2.1.101	8.7	
201.4, 201.4.2.101, 201.7, 201.7.9.2.101 e), 201.16, 201.101.1, 201.102.1, 201.103, 201.103.2	9.1	
201.9, 201.12.1.101, 201.12.2, 201.15, 202	9.2	The 4th indent of ER 9.2 is not addressed.
201.11, 201.13	9.3	
201.7.9.2.101 d), 201.12, 201.101, 201.102, 201.103	10.1	
201.12.2	10.2	
201.7	10.3	