SLOVENSKI STANDARD
SIST EN ISO 80601-2-13:2013

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Nadomešča:
SIST EN ISO 8835-2:2009
SIST EN ISO 8835-3:2009
SIST EN ISO 8835-3:2009/A1:2011
SIST EN ISO 8835-4:2009
SIST EN ISO 8835-5:2009

Medicinska električna oprema - 2-13: del: Posebne zahteve za osnovno varnost in bistvene lastnosti delovnega mesta za anestezijo (ISO 80601-2-13:2011)

Medical electrical equipment - Part 2-13: Particular requirements for basic safety and essential performance of an anaesthetic workstation (ISO 80601-2-13:2011)

Medizinische elektrische Geräte - Teil 2-13: Besondere Festlegungen für die Sicherheit einschließlich der wesentlichen Leistungsmerkmale von Anästhesie-Arbeitsplätzen (ISO 80601-2-13:2011)

Appareils électromédicaux - Partie 2-13: Exigences particulières de sécurité de base et de performance essentielle pour les systèmes d'anesthésie (ISO 80601-2-13:2011)

Ta slovenski standard je istoveten z: **EN ISO 80601-2-13:2012**

ICS:

11.040.10	Anestezijska, respiratorna in reanimacijska oprema	Anaesthetic, respiratory and reanimation equipment

SIST EN ISO 80601-2-13:2013 **en**

EUROPEAN STANDARD
NORME EUROPÉENNE
EUROPÄISCHE NORM

EN ISO 80601-2-13

December 2012

ICS 11.040.10

Supersedes EN ISO 8835-2:2009, EN ISO 8835-3:2009,
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EN 60601-2-13:2006

English Version

Medical electrical equipment - Part 2-13: Particular requirements for basic safety and essential performance of an anaesthetic workstation (ISO 80601-2-13:2011)

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This European Standard was approved by CEN on 18 November 2012.

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. Up-to-date lists and bibliographical references concerning such national standards may be obtained on application to the CEN-CENELEC Management Centre or to any CEN 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 CEN member into its own language and notified to the CEN-CENELEC Management Centre has the same status as the official versions.

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

Management Centre: Avenue Marnix 17, B-1000 Brussels

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Foreword

The text of ISO 80601-2-13:2011 has been prepared by Technical Committee ISO/TC 121 “Anaesthetic and respiratory equipment” of the International Organization for Standardization (ISO) and has been taken over as EN ISO 80601-2-13:2012 by Technical Committee CEN/TC 215 “Respiratory and anaesthetic equipment” the secretariat of which is held by BSI.

This European Standard shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by June 2013, and conflicting national standards shall be withdrawn at the latest by December 2015.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. CEN [and/or CENELEC] shall not be held responsible for identifying any or all such patent rights.

This document supersedes EN ISO 8835-2:2009, EN ISO 8835-3:2009, EN ISO 8835-4:2009, EN ISO 8835-5:2009, EN 60601-2-13:2006.

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.

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

According to the CEN/CENELEC Internal Regulations, the national standards organisations of the following countries are bound to implement this European Standard: Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, Former Yugoslav Republic of Macedonia, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and the United Kingdom.

Endorsement notice

The text of ISO 80601-2-13:2011 has been approved by CEN as a EN ISO 80601-2-13:2012 without any modification.

Annex ZA
(informative)

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

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 to conforming to Essential Requirements of the New Approach Directive 93/42/EEC, Council Directive of 14 June 1993 on the approximation of the laws of the Member States concerning medical devices" (Medical Device Directive).

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

Clause(s)/subclause(s) of this EN	Corresponding essential requirements of Directive 93/42/EEC	Qualifying remarks/ynotes
201.11.6.8; 201.102.3; 201.104.7	7.2	only the risks to patients during NORMAL USE are addressed
201.11.6.3; 201.11.6.8	7.3	
201.7.2.105, 201.7.9.2.14	7.5, 2nd and 3rd paragraph	
201.101.4.1.2; 201.11.6.3	7.6	IP classification according IEC 60529 is governed by EN 60601-1:2006
201.11.101; 201.104.7	8.1	Easy handling and contamination by the patients are not addressed.
201.11.101	8.6	
201.16.9.2.1; 201.16.101; 201.101.3; 201.101.4.1 201.101.4.2; 201.101.9; 201.102.5; 201.102.9; 201.103.4 to 201.103.7; 201.104.4; 201.104.5, 201.104.6; 201.105.4; 201.105.6	9.1	
201.9.4; 201.9.4.2.4.3; 201.105.7, 202; 209	9.2 (First and second indents)	Clause 202 refers to EN 60601-1-2:2007, Clause 209 refers to EN 60601-1-9:2008
201.11; 201.102.4	9.3	
201.12.4.104.1; 201.101.6.1; 201.104.2.2	10.1	

Clause(s)/subclause(s) of this EN	Corresponding essential requirements of Directive 93/42/EEC	Qualifying remarks/ynotes
201.7.4.2;	10.2	
201.7.4.3	10.3	
201.14	12.1	EN 62304:2006, 1.4
201.14, 201.14.101	12.1 a)	EN 62304:2006, 1.4
201.11.8.102; 201.11.8.103	12.2	
201.11.8.102	12.3	
201.12.4.104.2; 201.12.4.105; 201.12.4.106; 208	12.4	Clause 208 refers to EN 60601-1-8:2006
202	12.5	Clause 202 refers to EN 60601-1-2:2007
201.9	12.7.1	
201.9, 201.9.2.103	12.7.2	
201.9, 201.11.8.102	12.7.3	
201.15, 201.16, 201.101.4.2.1	12.7.4	Covered by compliance with EN 60601-1:2006, 15.4.1 and 16.9
201.11	12.7.5	EN 60601-1:2006, Clause 11
201.101.4.1.3; 201.101.6.2; 201.101.6.3; 201.102.2.1; 201.102.2.2; 201.102.10.4; 201.104.2.1; 201.104.5; 201.105.2.1; 201.105.2.2;	12.8.1	
201.12.4.104.2; 201.12.4.106; 201.12.4.107.1; 201.12.4.107.2; 201.12.4.107.3; 201.12.4.109; 201.101.2; 201.101.4.3; 201.102.10: 201.102.10.4; 201.104.5; 201.105.5; 201.105.8; 208	12.8.2	
201.101.6.1; 201.104.2.1;	12.9	
201.7, 201.7.2.104; 201.7.9.1; 201.102.1.1.1	13.1	
201.7, 201.7.2.3; 201.7.2.101; 201.7.2.103; 201.7.2.107; 201.7.4.2	13.2	
201.7.9.1	13.3 a)	
201.7.2.101	13.3 e)	

Clause(s)/subclause(s) of this EN	Corresponding essential requirements of Directive 93/42/EEC	Qualifying remarks/ynotes
201.7, 201.7.2.101	13.3 f)	The indication that the device is for single use must be consistent across the Community is not addressed in a requirement.
201.7, 201.7.9.3.102	13.3 i)	
201.7, 201.7.2 201.7.2.102, 201.7.2.103, 201.7.2.104 201.7.2.107 201.7.4.2 201.101.6.1 201.102.1.1.2 201.102.1.1.3 201.102.1.1.4 201.102.5.2 201.102.5.3 201.102.5.4 201.102.5.7 201.103.1.1 201.104.1.1 201.104.2.1 201.104.6 201.105.6	13.3 j)	
201.7, 201.7.2.3 201.104.1.1	13.3 k)	
201.7.2.101	13.3.l)	
201.7.2.102; 201.102.5.2; 201.102.5.4; 201.102.5.5; 201.102.5.6; 201.103.5; 201.103.6; 201.104.4	13.5	
201.7	13.6 a)	Covered by compliance with EN 60601-1:2006, 7.9.2
201.7	13.6 b)	Covered by compliance with EN 60601-1:2006, 7.9.2
201.7.9.2.1 201.7.9.2.14 201.11.8 201.11.8.101 201.11.8.103 201.12.4.102 201.12.4.103.3 201.12.4.106 201.12.4.107.2 201.12.4.108 201.101.1.1 201.101.1.2 201.102.1.2	13.6 c)	

Clause(s)/subclause(s) of this EN	Corresponding essential requirements of Directive 93/42/EEC	Qualifying remarks/ynotes
201.102.7 201.102.8.2 201.102.9.2 201.102.9.3 201.102.10.3 201.103.1.2 201.104.1.2 201.104.2.1 201.104.6 201.105.1 201.105.2.2 201.105.5		
201.7, 201.102.10.1 201.103.3.1.5 208.5.2.2	13.6 d)	maintenance and frequency covered by compliance with EN 60601-1:2006, 7.9.2.13
201.7.9.2.14	13.6 f)	
201.7 201.7.9.2.14	13.6 h), first paragraph only	Covered by compliance with EN 60601-1:2006, 7.9.2
201.7 201.7.9.2.1 201.7.9.2.8	13.6 i)	Covered by compliance with EN 60601-1:2006, 7.9
201.7.9.2.2 201.7.9.2.14	13.6 k)	
201.12.4.103 ; 201.12.4.104.1, 201.12.4.109; 201.101.6.1; 201.104.2.2;	13.6 p)	
201.7.9.2.1	13.6 q)	

For devices which are also machinery within the meaning of Article 2(a) of Directive 2006/42/EC on Machinery, in accordance with Article 3 of Directive 93/42/EEC the following table ZA.102 details the relevant essential health and safety requirements of Directive 2006/42/EC on Machinery to the extent to which they are more specific than essential requirements of Directive 93/42/EEC along with the corresponding clauses of this European Standard. Table ZA.102, however, does not imply any citation in the OJEU under the machinery directive and thus does not provide presumption of conformity for the machinery directive.

Table ZA.102 — Relevant Essential Requirements from Directive 2006/42/EC on machinery that are addressed by this European Standard
(according to article 3 of amended Directive 93/42/EEC)

Clause(s)/subclause(s) of this EN	EHSR of Directive 2006/42/EC	Qualifying remarks/notes
201.9.2.102	1.1.4	
201.9.2.103	1.1.8	
201.7.4.2 201.9.2 201.9.2.104 201.101.6.1 201.102.1.1.2 201.102.1.1.3 201.102.9.2 201.104.1.1 201.104.2.1 206 208	1.2.2	
201.101.3 201.101.4.1.1 201.101.4.1.2 201.101.9 201.102.5 201.102.8.1 201.102.9.1 201.103.4, 201.103.5; 201.103.6 201.103.7 201.104.4 201.105.4 201.105.6	1.5.4	
201.9.2.101	1.6.2	
201.8	1.6.3	
201.7 201.7.2.106	3.6.2	Covered by compliance with EN 60601-1:2006, 7.2

WARNING: Other requirements and other EU Directives may be applicable to the products falling within the scope of this European Standard.

INTERNATIONAL STANDARD

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Medical electrical equipment —

Part 2-13: Particular requirements for basic safety and essential performance of an anaesthetic workstation

Appareils électromédicaux —

Partie 2-13: Exigences particulières de sécurité de base et de performance essentielle pour les systèmes d'anesthésie

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ISO copyright office
Case postale 56 • CH-1211 Geneva 20
Tel. + 41 22 749 01 11
Fax + 41 22 749 09 47
E-mail copyright@iso.org
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