SLOVENSKI STANDARD
SIST EN ISO 8185:2009

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SIST EN ISO 8185:2008

Vlažilniki dihalnega trakta za uporabo v medicini - Posebne zahteve za dihalne vlažilne sisteme (ISO 8185:2007)

Respiratory tract humidifiers for medical use - Particular requirements for respiratory humidification systems (ISO 8185:2007)

Anfeuchter für Respirationsluft für medizinische Zwecke - Besondere Anforderungen an Anfeuchtersysteme für Respirationsluft (ISO 8185:2007)

Humidificateurs respiratoires médicaux - Exigences spécifiques des systèmes d'humidification respiratoires (ISO 8185:2007)

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ICS:

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

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EUROPEAN STANDARD

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Respiratory tract humidifiers for medical use - Particular requirements for respiratory humidification systems (ISO 8185:2007)

Humidificateurs respiratoires médicaux - Exigences spécifiques des systèmes d'humidification respiratoires (ISO 8185:2007)

Anfeuchter für Respirationsluft für medizinische Zwecke - Besondere Anforderungen an Anfeuchtersysteme für Respirationsluft (ISO 8185:2007)

This European Standard was approved by CEN on 21 March 2009.

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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 Management Centre has the same status as the official versions.

CEN members are the national standards bodies of Austria, Belgium, Bulgaria, 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 and United Kingdom.

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Foreword

The text of ISO 8185:2007 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 8185:2009 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 October 2009, and conflicting national standards shall be withdrawn at the latest by March 2010.

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 8185:2007.

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 EC Directive.

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

According to the CEN/CENELEC Internal Regulations, the national standards organizations of the following countries are bound to implement this European Standard: Austria, Belgium, Bulgaria, 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 and the United Kingdom.

Endorsement notice

The text of ISO 8185:2007 has been approved by CEN as a EN ISO 8185:2009 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 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 Communities 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 EU Directives

Clause(s)/sub-clause(s) of this EN	Essential Requirements (ERs) of Directive 93/42/EEC	Qualifying remarks/Notes
All	1 (first paragraph), 2, 3	
4 [3.6 cc)]	12.1	
6	13.1, 13.2, 13.3	And via IEC 60601-1, Clause 6
6.1 aa)	13.1	
6.1 d)	13.1, 13.2, 13.3 b)	
6.1 e)	13.1, 13.3 a)	
6.1 f)	13.1, 13.3 b)	
6.3	10.1, 10.3, 12.9	And via IEC 60601-1, Subclause 6.3
6.4, 6.5	13.2	
6.6	9.1	And via IEC 60601-1, Subclause 6.6
6.7	12.9	And via IEC 60601-1, Subclause 6.7
6.8.2	13.1	
6.8.2 a)	2, 13.3 k), 13.3 m), 13.4, 13.5, 13.6 a),13.6 b), 13.6 c), 13.6 d), 13.6 i), 13.6 j),13.6 o)	
6.8.2 d)	13.6 h)	
10.1	5	And via IEC 60601-1, Subclause 10.1

Clause(s)/sub-clause(s) of this International Standard	Essential requirements (ERs) of EU Directive 93/42/EEC	Qualifying remarks/Notes
10.2	4	
10.2.101	12.7.4	
15	12.6	Via IEC 60601-1, Clause 15
16	12.6	Via IEC 60601-1, Clause 16
17	12.6	Via IEC 60601-1, Clause 17
18	12.6	Via IEC 60601-1, Clause 18
19	12.6	Via IEC 60601-1, Clause 19
20	12.6	Via IEC 60601-1, Clause 20
21	4, 5, 9.2, 12.7.1	And via IEC 60601-1, Clause 21
22	12.7.1	Via 60601-1, Clause 22
23	4, 9.2, 12.7.1	Via IEC 60601-1, Clause 23
24	4, 12.7.1	And via IEC 60601-1, Clause 24
25	12.7.1	Via IEC 60601-1, Clause 25
26	12.7.2	Via IEC 60601-1, Clause 26
28	12.7.1	Via IEC 60601-1, Clause 28
29	11.3.1	Via IEC 60601-1, Clause 29
35	12.7.3	And via IEC 60601-1, Clause 35
35.101	4, 12.7.3	
36	4, 9.2, 12.5	And via IEC 60601-1, Clause 36
36.202.1	9.2	
37, 38, 39, 40, 41	9.3	
42	12.7.5	
42.101	4, 12.7.5, 12.8.1	
43	7.1, 9.3	And via IEC 60601-1, Clause 43
43.101	7.1, 7.3	
44	7.2, 7.5, 7.6	
44.2	7.2, 7.5	
44.3	7.6	
44.4	7.5	
44.6	7.6	
44.7	8.1, 8.4, 8.5	Via IEC 60601-1, Subclause 44.7

Clause(s)/sub-clause(s) of this International Standard	Essential requirements (ERs) of EU Directive 93/42/EEC	Qualifying remarks/Notes
44.8	7.1, 7.2, 7.3	
45	9.2	Via IEC 60601-1, Clause 45
46	10.2	Via IEC 60601-1, Clause 46
48	7.1	Via IEC 60601-1, Clause 48
49	4, 9.2	And via IEC 60601-1, Clause 49
50	10.1, 12.8.1	
50.1	12.9	
50.2	10.1, 10.2	
50.2 aa)	2, 12.8.1	
50.2 bb)	2, 12.8.1	
50.2 cc)	2, 12.8.2	
51	12.8.1	Via IEC 60601-1, Clause 51
51	4	
51.101, 51.102, 51.103	2, 12.8.1	
52	7.2, 7.6, 9.2, 9.3, 12.7.1	Via IEC 60601-1, Clause 52
56	9.1, 12.6, 12.7.5	And via IEC 60601-1, Clause 56
56.3	9.1, 12.7.5	
56.7	9.3	Via IEC 60601-1, Subclause 56.7
56.101	7.2, 7.3, 9.1, 12.8.1, 12.8.2, 13.5	
56.102	7.5, 9.1, 13.5	
57	12.6, 12.7.4	Via IEC 60601-1, Clause 57
58	12.6	Via IEC 60601-1, Clause 58
59	9.3, 12.6	Via IEC 60601-1, Clause 59
101	3, 4	
102	3, 10.2	
103	2, 9.1, 12.7.3, 12.9, 13.1, 13.2, 13.6 d)	Via IEC 60601-1, Clause 6 and via IEC60601-8
201	2	Via IEC 60601-8
-	1 (first paragraph and 2nd paragraph, 1st dash)	This relevant Essential Requirement is not addressed in this European Standard
-	1 (first paragraph and 2nd paragraph, 2nd dash)	This relevant Essential Requirement is not addressed in this European Standard
-	6a	This relevant Essential Requirement is not addressed in this European Standard

48	7.5 (1st paragraph)	This relevant Essential Requirement is not fully addressed in this European Standard
6.1	7.5 (2nd paragraph)	This relevant Essential Requirement is not fully addressed in this European Standard
6.8.2	7.5 (3rd paragraph)	This relevant Essential Requirement is not fully addressed in this European Standard
-	12.1a)	This relevant Essential Requirement is not addressed in this European Standard.
6.1	13.3 (a):	This relevant Essential Requirement is not fully addressed in this European Standard
6.1	13.3 (f)	This relevant Essential Requirement is not fully addressed in this European Standard
6.8.2	13.6 (h)(2nd paragraph)	This relevant Essential Requirement is not fully addressed in this European Standard
6.8.2	13.6 (h)(3rd paragraph)	This relevant Essential Requirement is not fully addressed in this European Standard
6.8.2	13.6 (q)	This relevant Essential Requirement is not addressed in this European Standard

WARNING: Other requirements and other EU Directives may be applicable to the product(s) falling within the scope of this standard.

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.2 details the relevant essential requirements of Directive 2006/42/EC on Machinery to the extent to which they are more specific than those of Directive 93/42/EEC along with the corresponding clauses of this European Standard. Table ZA.2, 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.2 – 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)/sub-clause(s) of this EN	Essential Health and Safety Requirements (EHSRs) of 2006/42/EC	Qualifying remarks/Notes
-	1.1.4 Lighting	This relevant EHSR is not addressed in this European Standard
50, 51	1.2.2 Control devices	This relevant EHSR is not fully addressed in this European Standard
6, 56	1.5.4 Errors of fitting	This relevant EHSR is not fully addressed in this European Standard
-	1.6.1 Machinery maintenance	This relevant EHSR is not addressed in this European Standard
-	1.6.2 Access to operating positions and servicing points	This relevant EHSR is not addressed in this European Standard
-	1.6.3 Isolation of energy sources	This relevant EHSR is not addressed in this European Standard
-	3.6.2 Marking	This relevant EHSR is not addressed in this European Standard

INTERNATIONAL STANDARD

ISO 8185

Third edition
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Respiratory tract humidifiers for medical use — Particular requirements for respiratory humidification systems

Humidificateurs respiratoires médicaux — Exigences spécifiques des systèmes d'humidification respiratoires

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Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 2.

The main task of technical committees is to prepare International Standards. Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

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

ISO 8185 was prepared by Technical Committee ISO/TC 121, *Anaesthetic and respiratory equipment*, Subcommittee SC 3, *Lung ventilators and related equipment*.

This third edition cancels and replaces the second edition (ISO 8185:1997), which has been technically revised. It also incorporates the Technical Corrigendum, ISO 8185:1997/Cor. 1:2001.

