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IRISH STANDARD

I.S. EN ISO 8185:2007

ICS 11.040.10

National Standards
Authority of Ireland
Glasnevin, Dublin 9
Ireland
Tel: +353 1 807 3800
Fax: +353 1 807 3838
http://www.nsai.ie

Sales
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RESPIRATORY TRACT HUMIDIFIERS FOR MEDICAL USE - PARTICULAR REQUIREMENTS FOR RESPIRATORY HUMIDIFICATION SYSTEMS (ISO 8185:2007)

This Irish Standard was published under the authority of the National Standards Authority of Ireland and comes into effect on:
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EUROPEAN STANDARD

NORME EUROPÉENNE

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EN ISO 8185

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Supersedes EN ISO 8185:1997

English Version

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 24 June 2007.

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 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 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.

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

Management Centre: rue de Stassart, 36 B-1050 Brussels

Ref. No. EN ISO 8185:2007: E

Foreword

This document (EN ISO 8185:2007) has been prepared by Technical Committee ISO/TC 121 "Anaesthetic and respiratory equipment" in collaboration with 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 January 2008, and conflicting national standards shall be withdrawn at the latest by January 2008.

This document supersedes EN ISO 8185:1997.

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.

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 United Kingdom.

Endorsement notice

The text of ISO 8185:2007 has been approved by CEN as EN ISO 8185:2007 without any modifications.

ANNEX ZA
(informative)

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

This International 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 International 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 International Standard given in Table ZA.1 confers, within the limits of the scope of this International Standard, a presumption of conformity with the corresponding Essential Requirements of that Directive and associated EFTA regulations.

Table ZA.1 — Correspondence between this International Standard and EU Directive 93/42/EEC

Clause(s)/sub-clause(s) of this International Standard	Essential requirements (ERs) of EU Directive 93/42/EEC	Qualifying remarks/Notes
All	1, 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