SVENSK STANDARD
SS-EN ISO 5359:2008/A1:2012

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Slangmontage för medicinska gaser vid låga tryck – Tillägg 1 (ISO 5359:2008/Amd 1:2011)

Low-pressure hose assemblies for use with medical gases – Amendment 1 (ISO 5359:2008/Amd 1:2011)

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Europastandarden EN ISO 5359:2008/A1:2011 gäller som svensk standard. Detta dokument innehåller den officiella engelska versionen av EN ISO 5359:2008/A1:2011.

The European Standard EN ISO 5359:2008/A1:2011 has the status of a Swedish Standard. This document contains the official version of EN ISO 5359:2008/A1:2011.

Upplysningar om sakinnehållet i standarden lämnas av SIS, Swedish Standards Institute, telefon 08-555 520 00. Standarder kan beställas hos SIS Förlag AB som även lämnar allmänna upplysningar om svensk och utländsk standard.

Information about the content of the standard is available from the Swedish Standards Institute (SIS), telephone +46 8 555 520 00. Standards may be ordered from SIS Förlag AB, who can also provide general information about Swedish and foreign standards.

Denna standard är framtagen av kommittén för Anestesi- och respiratorutrustning, SIS/TK 329.

Har du synpunkter på innehållet i den här standarden, vill du delta i ett kommande revideringsarbete eller vara med och ta fram andra standarder inom området? Gå in på www.sis.se - där hittar du mer information.

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN ISO 5359:2008/A1

December 2011

ICS 83.140.40; 11.040.10

English Version

Low-pressure hose assemblies for use with medical gases - Amendment 1 (ISO 5359:2008/Amd 1:2011)

Flexibles de raccordement à basse pression pour utilisation avec les gaz médicaux - Amendement 1 (ISO 5359:2008/Amd 1:2011)

Niederdruck-Schlauchleitungssysteme zur Verwendung mit medizinischen Gasen - Änderung 1 (ISO 5359:2008/Amd 1:2011)

This amendment A1 modifies the European Standard EN ISO 5359:2008; it was approved by CEN on 14 December 2011.

CEN members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for inclusion of this amendment into the relevant 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 amendment 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.

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 and United Kingdom.

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

Management Centre: Avenue Marnix 17, B-1000 Brussels

Ref. No. EN ISO 5359:2008/A1:2011: E

Foreword

This document (EN ISO 5359:2008/A1:2011) 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 June 2012, and conflicting national standards shall be withdrawn at the latest by June 2012.

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 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 organizations of the following countries are bound to implement this European Standard: 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 and the United Kingdom.

Endorsement notice

The text of ISO 5359:2008/Amd 1:2011 has been approved by CEN as a EN ISO 5359:2008/A1:2011 without any modification.

Low-pressure hose assemblies for use with medical gases

AMENDMENT 1

Page 13, Table 1

Change the allocation of connectors B11 and C19 as follows in order to align the allocation of these connectors with the corresponding allocation of NIST connectors, as given in EN 15908:2010.

B11: “Carbon dioxide” instead of “Carbon dioxide/oxygen mixture [$CO_2 > 7$ % (volume fraction)]”.

C19: “Carbon dioxide/oxygen mixture [$CO_2 > 7$ % (volume fraction)]” instead of “Carbon dioxide”.

Page 28, Bibliography

Add the following reference:

[18] EN 15908:2010, *Anaesthetic and respiratory equipment — Non-interchangeable screw-threaded (NIST) low-pressure connectors for medical gases*

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 one means of conforming to Essential Requirements of the New Approach Directive 93/42/EEC 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 normative 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 Medical devices

Clause(s)/sub-clause(s) of this European Standard	Essential Requirements (ERs) of Directive 93/42/EEC	Qualifying remarks/Notes
4	1	
4.1	2.6	
4.2	2	
4.3.1	7.1, 7.3, 9.3	
4.3.2	4, 7.1, 9.2	
4.3.3	3, 5, 7.2	
4.4.2	9.1, 9.2, 12.7.1	
4.4.3	9.2	
4.4.4	12.7.1, 12.8.1	
4.4.7	9.1, 12.7.4	
4.4.8	9.1, 12.7.4	
4.4.9	9.1, 12.7.4	
4.4.13	7.5	
4.4.14	9.1	
4.5.1	7.2, 9.3	
4.5.2	9.3	
5.2	9.1	
5.3	7.5	
5.4	9.1, 12.7.4	
5.5	9.1, 9.2, 12.7.1	
5.6	9.2	
5.7	12.7.1, 12.8.1	
5.8	13.2	
6.1	13.2	
6.1.3	13.1, 13.3 a), 13.3 d), 13.5	
6.1.5	13.3 e)	
6.2	13.2	
6.3.1	5, 7.2, 7.6	
6.3.2	13.1, 13.3 b)	
7	2, 13.1, 13.3 a), 13.4, 13.6 d)	

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