SLOVENSKI STANDARD
SIST EN ISO 5359:2008/A1:2012

01-marec-2012

Nizkotlačne povezovalne cevi za delo z medicinskimi plini - Dopolnilo A1 (ISO 5359:2008/Amd 1:2011)

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

Niederdruck-Schlauchleitungssysteme zur Verwendung mit medizinischen Gasen (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)

Ta slovenski standard je istoveten z: **EN ISO 5359:2008/A1:2011**

ICS:

11.040.10	Anestezijska, respiratorna in reanimacijska oprema	Anaesthetic, respiratory and reanimation equipment
83.140.40	Gumene cevi	Hoses

SIST EN ISO 5359:2008/A1:2012 **en**

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN ISO 5359:2008/A1

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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.

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

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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.

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.

INTERNATIONAL STANDARD

ISO 5359

Third edition
2008-06-15

AMENDMENT 1
2011-12-15

Low-pressure hose assemblies for use with medical gases

AMENDMENT 1

Flexibles de raccordement à basse pression pour utilisation avec les gaz médicaux

AMENDEMENT 1

Reference number
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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.

Amendment 1 to ISO 5359:2008 was prepared by Technical Committee ISO/TC 121, *Anaesthetic and respiratory equipment*, Subcommittee SC 1, *Breathing attachments and anaesthetic machines*.