SLOVENSKI STANDARD
SIST EN ISO 5359:2008

01-september-2008

Nadomešča:
SIST EN 739:2000
SIST EN 739:2000/A1:2002

Nizkotlačne povezovalne cevi za delo z medicinskimi plini (ISO 5359:2008)

Low-pressure hose assemblies for use with medical gases (ISO 5359:2008)

Niederdruckschlauchleitungssysteme zur Verwendung mit medizinischen Gasen (ISO 5359:2008)

Flexibles basse pression utilisés dans les systemes de gaz médicaux (ISO 5359:2008)

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

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 **en**

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN ISO 5359

June 2008

ICS 83.140.40; 11.040.10

Supersedes EN 739:1998

English Version

Low-pressure hose assemblies for use with medical gases (ISO 5359:2008)

Flexibles de raccordement à basse pression pour utilisation avec les gaz médicaux (ISO 5359:2008)

Niederdruck-Schlauchleitungssysteme zur Verwendung mit medizinischen Gasen (ISO 5359:2008)

This European Standard was approved by CEN on 29 May 2008.

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 5359:2008: E

Contents

Page

Foreword

This document (EN ISO 5359:2008) 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 December 2008, and conflicting national standards shall be withdrawn at the latest by June 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 739:1998.

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(s).

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 5359:2008 has been approved by CEN as a EN ISO 5359:2008 without any modification.

Annex ZA
(informative)

Relationship between this International 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 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 Communities 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 International Standard and Directive 93/42/EEC Medical devices

Clause(s)/sub-clause(s) of this International 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

Low-pressure hose assemblies for use with medical gases

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

Reference number
ISO 5359:2008(E)

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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
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Contents

Page

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

This third edition cancels and replaces the second edition (ISO 5359:2000), which has been technically revised.

Introduction

0.1 General

This International Standard has been prepared in response to the need for a safe method of connecting medical equipment to a fixed medical gas pipeline system or other medical gas supply system such that hose assemblies carrying different gases, or the same gas at different pressures, cannot be interchanged. Fixed medical gas pipelines, once installed, are rarely disturbed and are subjected to commissioning procedures to avoid the possibility of cross-connections or contamination of the medical gas conveyed. However, hose assemblies are subjected to physical wear and tear, misuse and abuse throughout their relatively short service life and are frequently connected to, and disconnected from, the medical equipment and the fixed pipeline.

While recognising that no system is absolutely safe, this International Standard includes those requirements considered necessary to prevent foreseeable hazards arising from the use of hose assemblies. Operators should be continually alert to the possibility of damage being caused by external factors, and therefore regular inspection and repair should be undertaken to ensure that hose assemblies continue to meet the requirements of this International Standard.

This International Standard pays particular attention to:

— suitability of materials;

— gas-specificity;

— cleanliness;

— testing;

— identification;

— information supplied.

Rationales for some of the requirements of this International Standard are given in Annex A. Such requirements are indicated by the asterisk (*) after the clause number in the main text.

0.2 Standardization of screw-threaded connectors for use in hose assemblies

Whilst the desirability of achieving agreement on a single International Standard for screw-threaded connectors has never been in doubt, the present pattern of usage has made such agreement impossible. Nevertheless, fears that proliferation of individual national standards or practices will eventually result in potentially dangerous cross-connection between components for different gases have led to the choice of three screw-threaded connector systems for inclusion in this International Standard.

The three systems of connectors, which are non-interchangeable, are diameter-index safety system (DISS), non-interchangeable screw-threaded (NIST) and sleeve indexed system (SIS). Tables 1 and 5 detail those gases and gas mixtures for which DISS, NIST and SIS connectors have been allocated. Dimensions of NIST connectors are given in Tables 2, 3 and 4 and Figures 2, 3, 4 and 5. Dimensions of DISS connectors can be obtained from the Compressed Gas Association Inc., 1725 Jefferson Davis Highway, Arlington, VA 22202, USA. Dimensions of SIS connectors can be obtained from Standards Australia, GPO Box 476 Sydney, New South Wales, 2001, Australia.

As an alternative to the screw-threaded connector, a “quick connector” which is gas-specific can be used at the inlet (outlet for vacuum) of the hose assembly, i.e. to connect the hose assembly to the fixed pipeline. Quick-connector systems of differing design should be non-interchangeable with each other in any one health-care facility.