

**Meditiiniliste gaaside jaoks kasutatavad
madalrõhu voolikukomplektid**

Low-pressure hose assemblies for use with medical
gases

EESTI STANDARDI EESSÕNA

NATIONAL FOREWORD

<p>Käesolev Eesti standard EVS-EN ISO 5359:2008 sisaldab Euroopa standardi EN ISO 5359:2008 ingliskeelset teksti.</p> <p>Standard on kinnitatud Eesti Standardikeskuse 21.07.2008 käskkirjaga ja jõustub sellekohase teate avaldamisel EVS Teatajas.</p> <p>Euroopa standardimisorganisatsioonide poolt rahvuslikele liikmetele Euroopa standardi teksti kättesaadavaks tegemise kuupäev on 15.06.2008.</p> <p>Standard on kättesaadav Eesti standardiorganisatsioonist.</p>	<p>This Estonian standard EVS-EN ISO 5359:2008 consists of the English text of the European standard EN ISO 5359:2008.</p> <p>This standard is ratified with the order of Estonian Centre for Standardisation dated 21.07.2008 and is endorsed with the notification published in the official bulletin of the Estonian national standardisation organisation.</p> <p>Date of Availability of the European standard text 15.06.2008.</p> <p>The standard is available from Estonian standardisation organisation.</p>
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ICS 11.040.10, 83.140.40

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EUROPEAN STANDARD

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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.

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COMITÉ EUROPÉEN DE NORMALISATION
EUROPÄISCHES KOMITEE FÜR NORMUNG

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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of an identical text or by endorsement, at the latest by December 2008, and conflicting national standards shall be withdrawn at the latest by June 2010.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.

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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.

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Low-pressure hose assemblies for use with medical gases

1 Scope

1.1 * This International Standard specifies requirements for low-pressure hose assemblies intended for use with the following medical gases:

- oxygen;
- nitrous oxide;
- medical air;
- helium;
- carbon dioxide;
- xenon;
- specified mixtures of the gases listed above;
- oxygen-enriched air;
- air for driving surgical tools;
- nitrogen for driving surgical tools;
- vacuum.

It is intended in particular to ensure gas-specificity and to prevent cross-connection between systems conveying different gases. These hose assemblies are intended for use at maximum operating pressures of less than 1 400 kPa.

1.2 This International Standard specifies the allocation of (NIST), (DISS), (SIS) connectors to medical gases and specifies the dimensions of non-interchangeable screw-threaded (NIST) connectors.

1.3 This International Standard does not specify:

- requirements for coaxial hoses used for the supply and disposal of air for driving surgical tools;
- requirements for electrical conductivity.

1.4 This International Standard does not specify the intended uses of hose assemblies.

NOTE Some examples of intended use specified in other International Standards are as follows:

- a) between a terminal unit and medical equipment (ISO 9170-1, IEC 60601-2-12^[7], IEC 60601-2-13^[8]);
- b) between the fixed pipeline system and a terminal unit of that system (ISO 7396-1^[10], ISO 11197^[13]);

- c) between a terminal unit and a second terminal unit (ISO 7396-1);
- d) between an emergency supply and an emergency and maintenance inlet point of a pipeline system (ISO 10524-1^[12], ISO 7396-1);
- e) between an emergency supply and medical equipment (ISO 10524-1, ISO 10524-3^[16], IEC 60601-2-12, IEC 60601-2-13).

2 Normative references

The following referenced documents are indispensable for the application of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 1307, *Rubber and plastics hoses — Hose sizes, minimum and maximum inside diameters, and tolerances on cut-to-length hoses*

ISO 1402, *Rubber and plastics hoses and hose assemblies — Hydrostatic testing*

ISO 8033, *Rubber and plastics hoses — Determination of adhesion between components*

ISO 9170-1, *Terminal units for medical gas pipeline systems — Part 1: Terminal units for use with compressed medical gases and vacuum*

ISO 14971, *Medical devices — Application of risk management to medical devices*

ISO 15001, *Anaesthetic and respiratory equipment — Compatibility with oxygen*

EN 1089-3:2004, *Transportable gas cylinders — Gas cylinder identification (excluding LPG) — Part 3: Colour coding*

AS 2896-1998, *Medical gas systems — Installations and testing of non-flammable medical gas pipeline systems*

3 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

Examples of use of some of these terms to describe permitted inlet and outlet connectors for hose assemblies are given in Figure 1.

3.1

DISS connector

diameter-index safety system connector

any of a range of male and female components intended to maintain gas-specificity by the allocation of a set of different diameters to the mating connectors for each particular gas

3.2

gas-specific

having characteristics which prevent interchangeability, thereby allowing assignment to only one gas service or vacuum service

3.3

hose assembly check valve

valve which is normally closed and which allows flow in either direction when opened by the insertion of an appropriate gas-specific connector