High-pressure flexible connections for use with medical gas systems

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EESTI STANDARDI EESSÕNA **NATIONAL FOREWORD**

Käesolev Eesti standard EVS-EN ISO 21969:2006 sisaldab Euroopa standardi EN ISO 21969:2006 ingliskeelset teksti. Käesolev dokument on jõustatud 31.07.2006 ja selle kohta on avaldatud teade Eesti standardiorganisatsiooni ametlikus väljaandes. Standard on kättesaadav Eesti standardiorganisatsioonist.	This Estonian standard EVS-EN ISO 21969:2006 consists of the English text of the European standard EN ISO 21969:2006. This document is endorsed on 31.07.2006 with the notification being published in the official publication of the Estonian national standardisation organisation. The standard is available from Estonian standardisation organisation.

Käsitlusala: This International Standard applies to high-pressure flexible connections intended to be connected to cylinders or cylinder bundles with nominal filling pressures up to 25 000 kPa at 15 °C for use with the following medical gases:- oxygen; - nitrous oxide; - air for breathing;	**Scope:** This International Standard applies to high-pressure flexible connections intended to be connected to cylinders or cylinder bundles with nominal filling pressures up to 25 000 kPa at 15 °C for use with the following medical gases:- oxygen; - nitrous oxide; - air for breathing;

ICS 11.040.10

Võtmesõnad:

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English Version

High-pressure flexible connections for use with medical gas systems (ISO 21969:2005)

Raccords flexibles haute pression pour utilisation avec les systèmes de gaz médicaux (ISO 21969:2005)

Flexible Hochdruck-Verbindungen zur Verwendung in Systemen für medizinische Gase (ISO 21969:2005)

This European Standard was approved by CEN on 25 May 2006.

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 Central Secretariat 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 Central Secretariat has the same status as the official versions.

CEN members are the national standards bodies of Austria, Belgium, 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

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Foreword

The text of ISO 21969:2005 has been prepared by Technical Committee ISO/TC 121 “Anaesthetic and respiratory equipment” of the International Organization for Standardization (ISO) and has been taken over as EN ISO 21969:2006 by 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 2006, and conflicting national standards shall be withdrawn at the latest by December 2006.

This document supersedes EN 13221:2000.

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, 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 21969:2005 has been approved by CEN as EN ISO 21969:2006 without any modifications.

Annex ZA
(informative)

Relationship between this European Standard and the Essential Requirements of EU Directive 93/42/EEC Medical devices

This European Standard has been prepared under a mandate given to CEN by the European Commission and the European Free Trade Association to provide a 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 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 EN	Essential Requirements (ERs) of Directive 93/42/EEC	Qualifying remarks/Notes
5	1, 2, 3, 4, 5	
5.1	7.1, 7.2, 7.3, 9.3	
5.3.1	7.1, 7.3, 9.3	
5.3.2	7.1	
5.3.3	3, 4	
5.3.4	3, 4, 5	
5.4.1	7.5, 7.6, 9.1, 12.7.4	
5.4.2	7.5, 7.6, 9.1, 12.7.4	
5.4.3	4, 12.7.1	
5.4.4	3	
5.4.5	7.5, 9.3	
5.4.6	4, 9.2, 9.3, 12.7.1	
5.4.7	4, 9.2, 9.3, 12.7.1	
5.4.8	7.1, 9.3	
5.4.9	12.7.1	
5.4.10	1, 2, 3	
5.5.1	7.1, 9.1, 12.7.1	
5.5.2	7.1, 7.2, 7.3, 9.3	
7.1.1	13.1, 13.2	
7.1.2	13.3 a), 13.6 b), 13.3 d), 13.5	
7.2	13.2	
7.3.1	3, 5, 7.2, 7.6	

7.3.2	13.3 b)	
8	2, 5, 9.1, 13.1, 13.4, 13.6 c), 13.6 d), 13.3 i), 13.3 j), 13.3 k)	

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

INTERNATIONAL STANDARD

ISO 21969

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2005-03-01

High-pressure flexible connections for use with medical gas systems

Raccords flexibles haute pression pour utilisation avec les systèmes de gaz médicaux

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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
E-mail copyright@iso.org
Web www.iso.org

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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.

ISO 21969 was prepared by Technical Committee ISO/TC 121, *Anaesthetic and respiratory equipment*, Subcommittee SC 6, *Medical gas systems*.

Introduction

High-pressure flexible connections are widely used within a source of supply of a medical gas pipeline system to connect cylinders or cylinder bundles to a manifold. They may also be used to connect medical gas cylinders to the inlet ports of medical equipment fitted with integral pressure regulators suitable for high pressures.

Because of the high pressures to which these devices are subjected it is important that their characteristics be specified and tested in a defined manner. It is essential that regular inspection and maintenance be undertaken to ensure that high-pressure flexible connections continue to meet the requirements of this International Standard.

This International Standard pays particular attention to:

— use of suitable materials;

— safety (leakage, mechanical strength, bursting pressure and resistance to ignition);

— gas specificity;

— cleanliness;

— type testing;

— marking;

— information to be supplied by the manufacturer.

Annex A contains rationale statements for some of the requirements of this International Standard. It is included to provide additional insight into the reasoning that led to the requirements and recommendations that have been incorporated in this International Standard. The clauses and subclauses marked with an asterisk (*) after their number have corresponding rationale contained in Annex A. It is considered that knowledge of the reasons for the requirements will not only facilitate the proper application of this International Standard, but also will expedite any subsequent revision.

High-pressure flexible connections for use with medical gas systems

1 Scope

1.1 This International Standard applies to high-pressure flexible connections intended to be connected to cylinders or cylinder bundles with nominal filling pressures up to 25 000 kPa at 15 °C for use with the following medical gases:

— oxygen;

— nitrous oxide;

— air for breathing;

— helium;

— carbon dioxide;

— xenon;

— mixtures of the gases listed above;

— air for driving surgical tools;

— nitrogen for driving surgical tools.

1.2 This International Standard applies to high-pressure flexible connections intended to connect cylinders or cylinder bundles to manifolds within sources of supply of medical gas pipeline systems complying with ISO 7396-1.

1.3 This International Standard applies to high-pressure flexible connections intended to connect a cylinder to an inlet port of medical equipment (e.g. anaesthetic workstation or lung ventilator) fitted with an integral pressure regulator complying with ISO 10524-1.

1.4 This International Standard does not apply to high-pressure flexible connections intended to be used to fill cylinders nor does it apply to low-pressure flexible hose assemblies that are covered by ISO 5359.

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 32:1977, *Gas cylinders for medical use — Marking for identification of content*

ISO 407:2004, *Small medical gas cylinders — Pin-index yoke-type valve connections*

ISO 5145:2004, *Cylinder valve outlets for gases and gas mixtures — Selection and dimensioning*

ISO 7396-1:2002, *Medical gas pipeline systems — Part 1: Pipelines for compressed medical gases and vacuum*

ISO/TR 7470:1988, *Valve outlets for gas cylinders — List of provisions which are either standardized or in use*

ISO 10524-1:—[1)], *Pressure regulators for use with medical gas systems — Part 1: Pressure regulators and pressure regulators with flow-metering devices*

ISO 14971:2000, *Medical devices — Application of risk management to medical devices*

ISO 15001:2003, *Anaesthetic and respiratory equipment — Compatibility with oxygen*

3 Terms and definitions

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

3.1
cylinder bundle
group of interconnected cylinders with a single connector for filling and emptying

3.2
gas-specific
having characteristics which prevent connection between different gas services

3.3
manifold
device for connecting the outlet(s) of one or more cylinders or cylinder bundles of the same medical gas to the pipeline system

3.4
medical gas
any gas or mixture of gases intended to be administered to patients for anaesthetic, therapeutic, diagnostic or prophylactic purposes or for driving surgical tools

3.5
nominal inlet pressure
P_1
pressure for which the high-pressure flexible connection is intended to be used

NOTE P_1 is specified by the manufacturer.

3.6
single fault condition
condition in which a single means for protection against a safety hazard in equipment is defective or a single external abnormal condition is present

NOTE This definition was taken from IEC 60601-1.

1) To be published.