Paindliitmikud kõrgsurve meditsiinigaasi süsteemidele

High-pressure flexible connections for use with medical gas systems

EESTI STANDARDIKESKUS
ESTONIAN CENTRE FOR STANDARDISATION

EESTI STANDARDI EESSÕNA

NATIONAL FOREWORD

Käesolev Eesti standard EVS-EN ISO 21969:2009 sisaldab Euroopa standardi EN ISO 21969:2009 ingliskeelset teksti.	This Estonian standard EVS-EN ISO 21969:2009 consists of the English text of the European standard EN ISO 21969:2009.
Standard on kinnitatud Eesti Standardikeskuse 31.12.2009 käskkirjaga ja jõustub sellekohase teate avaldamisel EVS Teatajas.	This standard is ratified with the order of Estonian Centre for Standardisation dated 31.12.2009 and is endorsed with the notification published in the official bulletin of the Estonian national standardisation organisation.
Euroopa standardimisorganisatsioonide poolt rahvuslikele liikmetele Euroopa standardi teksti kättesaadavaks tegemise kuupäev on 01.11.2009.	Date of Availability of the European standard text 01.11.2009.
Standard on kättesaadav Eesti standardiorganisatsioonist.	The standard is available from Estonian standardisation organisation.

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EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN ISO 21969

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Supersedes EN ISO 21969:2006

English Version

High-pressure flexible connections for use with medical gas systems (ISO 21969:2009)

Raccords flexibles haute pression pour utilisation avec les systèmes de gaz médicaux (ISO 21969:2009)

Flexible Hochdruck-Verbindungen zur Verwendung in Systemen für medizinische Gase (ISO 21969:2009)

This European Standard was approved by CEN on 8 September 2009.

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.

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

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Ref. No. EN ISO 21969:2009: E

Foreword

This document (EN ISO 21969:2009) 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 May 2010, and conflicting national standards shall be withdrawn at the latest by May 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 ISO 21969:2006.

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, 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 21969:2009 has been approved by CEN as a EN ISO 21969:2009 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 a means of conforming to Essential Requirements of the New Approach Directive 93/42/EEC on 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 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

Clause(s)/sub-clause(s) of this International Standard	Essential Requirements (ERs) of Directive 93/42/EEC9/EC	Qualifying remarks/Notes (s) of 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	
6.2.1	7.5	
7.1.1	13.1, 13.2	
7.1.2	13.3a), 13.6b), 13.3d), 13.5	ER 13.3a) relating to the authorised representative is not fully addressed
7.2	13.2	
7.3.1	3, 5, 7.2, 7.6	
7.3.2	13.3b)	
8	1, 2, 5, 9.1, 13.1, 13.4, 13.6c), 13.6d),13.3i), 13.3j), 13.3k)	
-	13.6q)	ER 13.3q) relating to the date of issue of the last instructions for use is not addressed

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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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;

— oxygen-enriched air.

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 7396-1:2007, *Medical gas pipeline systems — Part 1: Pipeline systems for compressed medical gases and vacuum*

ISO 14971:2007, *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
pack or pallet of cylinders linked together with one or more connectors 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 gas to the pipeline system

3.4
medical gas
any gas or mixture of gases intended for administration to patients for anaesthetic, therapeutic, diagnostic or prophylactic purposes

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.