Irish Standard
I.S. EN ISO 21969:2009

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

I.S. EN ISO 21969:2009

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I.S. EN ISO 21969:2009

EUROPEAN STANDARD

NORME EUROPÉENNE

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EN ISO 21969

November 2009

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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.

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

Management Centre: Avenue Marnix 17, B-1000 Brussels

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of an identical text or by endorsement, at the latest by May 2010, and conflicting national standards shall be withdrawn at the latest by May 2010.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

I.S. EN ISO 21969:2009

INTERNATIONAL STANDARD

ISO 21969

Second edition
2009-11-01

High-pressure flexible connections for use with medical gas systems

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

Reference number
ISO 21969:2009(E)

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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*.

This second edition cancels and replaces the first edition (ISO 21969:2005) which has been technically revised.

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 will also 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;

— 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.