SLOVENSKI STANDARD
SIST EN ISO 21969:2006

01-september-2006

Nadomeġļa:
SIST EN 13221:2000

Visokotlaļni prilagodljivi priključki za uporabo medicinskih plinskih sistemov (ISO 21969:2005)

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

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

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

Ta slovenski standard je istoveten z: **EN ISO 21969:2006**

ICS:

11.040.10	Anestezijska, respiratorna in reanimacijska oprema	Anaesthetic, respiratory and reanimation equipment

SIST EN ISO 21969:2006 **en**

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN ISO 21969

June 2006

ICS 11.040.10

Supersedes EN 13221:2000

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

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Ref. No. EN ISO 21969:2006: E

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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 2007.

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

First edition
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

Reference number
ISO 21969:2005(E)

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