Kõrgsurve paindühendused kasutamiseks meditsiiniliste gaasidega

High- pressure flexible connections for use with medical gases



EESTI STANDARDI EESSÕNA

NATIONAL FOREWORD

Käesolev Eesti standard EVS-EN 13221:2000 sisaldab Euroopa standardi EN 13221:2000 ingliskeelset teksti.

Käesolev dokument on jõustatud 08.08.2000 ja selle kohta on avaldatud teade Eesti standardiorganisatsiooni ametlikus väljaandes.

Standard on kättesaadav Eesti standardiorganisatsioonist.

This Estonian standard EVS-EN 13221:2000 consists of the English text of the European standard EN 13221:2000.

This document is endorsed on 08.08.2000 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 Standard applies to high pressure flexible connections intended to be connected to cylinders with a working pressure up to 23.000 kPa for use with the following medical gases: oxygen, nitrous oxide, air for breathing, helium, carbon dioxide, xenon, specified mixtures of gases listed above air for driving surgical tools nitrogen for driving surgical tools.

Scope:

This Standard applies to high pressure flexible connections intended to be connected to cylinders with a working pressure up to 23.000 kPa for use with the following medical gases: oxygen, nitrous oxide, air for breathing, helium, carbon dioxide, xenon, specified mixtures of gases listed above air for driving surgical tools nitrogen for driving surgical tools.

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Võtmesõnad:

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English version

High-pressure flexible connections for use with medical gases

Raccords flexibles haute pression pour utilisation avec les gaz médicaux

Flexible Hochdruck-Verbindungen zur Verwendung mit medizinischen Gasen

This European Standard was approved by CEN on 2000-01-06.

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.

The European Standards exist 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, the Czech Republic, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Luxembourg, the Netherlands, Norway, Portugal, Spain, Sweden, Switzerland, and the United Kingdom.

CEN

European Committee for Standardization Comité Européen de Normalisation Europäisches Komitee für Normung

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Foreword

This European Standard has been prepared 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 August 2000, and conflicting national standards shall be withdrawn at the latest by August 2000.

This European Standard 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 standard.

According to the CEN/CENELEC Internal Regulations, the national standards organizations of the following countries are bound to implement this European Standard: Austria, Belgium, Czech Republic, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Luxembourg, Netherlands, Norway, Portugal, Spain, Sweden, Switzerland and the United Kingdom.

No. No. No. October 1960 Octobe Annex A and ZA are for information only.

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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 the manifold. They may also be used to connect a medical gas cylinder to the inlet port of a medical equipment fitted with an integral pressure regulator suitable for high pressure.

Because of the high pressure to which these devices are submitted it is important that their characteristics are specified and tested in a defined manner.

It is essential that regular inspection and maintenance are undertaken to ensure that the high-pressure flexible connections continue to meet the requirements of this European Standard.

This European Standard pays particular attention to:

- Suitability of materials
- Safety (leakage, mechanical strength and resistance to ignition)
- Gas-specificity
- Cleanliness
- Testing
- Identification
- Information supplied

Rationales for some of the requirements of this European Standard are given in annex A. Such requirements are indicated by the letter "R" after the clause number

1 Scope

1.1 This European Standard applies to high-pressure flexible connections intended to be connected to cylinders or cylinder bundles with a working pressure up to 23 000 kPa for use with the following medical gases:

oxygen nitrous oxide air helium carbon dioxide xenon nitrogen specified mixtures of the gases listed above

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- 1.2 This European 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 EN 737-3.
- 1.3 This European Standard applies to high-pressure flexible connections intended to connect a cylinder to the inlet port of medical equipment (e.g. anaesthetic workstations or lung ventilators) fitted with an integral pressure regulator complying with EN 738-1.
- 1.4 This European Standard does not apply to high-pressure flexible connections intended to be used to fill cylinders.

2 Normative references

This European Standard incorporates, by dated or undated reference, provisions from other publications. These normative references are cited at the appropriate places in the text and the publications are listed hereafter. For dated references, subsequent amendments to or revision of any of these publications apply to this European Standard only when incorporated in it by amendment or revision. For undated references the latest edition of the publication referred to applies.

EN 739	Low-pressure hose assemblies for use with medical gases
EN 850:1996	Medical gas cylinders - Pin - index, yoke - type valve outlet connections for medical use
EN 1441	Medical devices - Risk analysis
ISO 5145	Cylinder valve outlets for gases and gas mixtures - Selection and dimensioning

3 Terms and definitions

For the purposes of this Standard the following terms and definitions apply:

3.1

cylinder bundle

pack or pallet of cylinders linked together with a single connector for filling and emptying.

3.2

qas-specific

having characteristics which prevent interchangeability and thereby allow assignment to one gas only.