



# SLOVENSKI STANDARD

## SIST EN 13221:2000

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### Visokotlačni prilagodljivi priključki za uporabo medicinskih plinov

High-pressure flexible connections for use with medical gases

Flexible Hochdruck-Verbindungen zur Verwendung mit medizinischen Gasen

Raccords flexibles haute pression pour utilisation avec les gaz médicaux

Ta slovenski standard je istoveten z: **EN 13221:2000**

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#### **ICS:**

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

EN 13221

NORME EUROPÉENNE

EUROPÄISCHE NORM

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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 6 January 2000.

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.

Although this European Standard has been developed in one language only in accordance with Resolution BT 74/1997 related to the one language experiment, it exists in accordance with CEN/CENELEC Internal Regulations in the three official versions (English, French, German).

CEN members are the national standards bodies of Austria, Belgium, Czech Republic, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Luxembourg, Netherlands, Norway, Portugal, Spain, Sweden, Switzerland and United Kingdom.

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

Central Secretariat: rue de Stassart, 36 B-1050 Brussels

## Contents

	Page
Foreword	3
Introduction	4
1 Scope	4
2 Normative references	5
3 Terms and definitions	5
4 Terminology	6
5 General requirements	6
6 Test methods	10
7 Marking, colour coding and packaging	11
8 Information to be supplied by the manufacturer	12
Annex A (informative) Rationale	18
Annex ZA (informative) Clauses of this European Standard addressing essential requirements or other provisions of EU Directives	19
Bibliography	21

## 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.

Annexes 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 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.

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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.

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

## 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

#### **gas-specific**

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

### 3.3

#### **high-pressure (HP)**

pressure greater than 1 400 kPa

### 3.4

#### **medical gas**

any gas or mixture of gases intended to be administered to patients for therapeutic, diagnostic or prophylactic purposes or for surgical tool application

### 3.5

#### **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

### 3.6

#### **working pressure, $P_1$**

rated maximum pressure for which the flexible connection is designed

## 4 Terminology

Typical examples of high-pressure flexible connections with terminology are given in Figure 1. Typical applications of high-pressure flexible connections are given in Figure 2.

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## 5 General requirements

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### 5.1 Safety

High-pressure flexible connections shall, when transported, stored, installed, operated in normal use and maintained according to the instructions of the manufacturer, cause no safety hazard which could be foreseen using risk analysis procedures in accordance with EN 1441 and which is connected with their intended application, in normal condition and in single fault condition.

### 5.2 *R* Alternative construction

High-pressure flexible connections and components or parts thereof using materials or having forms of construction different from those detailed in clause 5 of this European Standard shall be accepted if it can be demonstrated that an equivalent degree of safety is obtained.

Such evidence shall be provided by the manufacturer.

### 5.3 Materials

**5.3.1** The materials in contact with the gas shall be compatible with oxygen, the other medical gases and their mixtures in the temperature range specified in 5.3.3.



NOTE 1 Corrosion resistance includes resistance against moisture and surrounding materials.

NOTE 2 Compatibility with oxygen involves both combustibility and ease of ignition. Materials which burn in air will burn violently in pure oxygen. Many materials which do not burn in air will do so in pure oxygen, particularly under pressure. Similarly, materials which can be ignited in air require less energy to ignite in oxygen. Many such materials can be ignited by friction at a valve seat or by adiabatic compression produced when oxygen at high pressure is rapidly introduced into a system initially at low pressure.

NOTE 3 A standard, prEN 13159, Compatibility of medical equipment with oxygen, is in preparation by CEN/TC 215/WG3.

**5.3.2 R** Non-metallic flexible hoses, e.g. polymer-lined or rubber-reinforced flexible hoses, shall not be used.

**5.3.3** The materials shall permit the high-pressure flexible connections and their components to meet the requirements of 5.4 in the temperature range of  $-20\text{ }^{\circ}\text{C}$  to  $+60\text{ }^{\circ}\text{C}$ .

**5.3.4** High-pressure flexible connections shall be capable, while packed for transport and storage, of being exposed to environmental conditions as stated by the manufacturer.

**5.3.5 R** Evidence of conformity with the requirements of 5.3.1, 5.3.3 and 5.3.4 shall be provided by the manufacturer.

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## 5.4 Design requirements

### 5.4.1 Inlet connector

The inlet connector, for connection to the cylinder valve, shall be gas-specific and conform to EN 850, ISO 5145 or the relevant national standard (see ISO/TR 7470 for information).

### 5.4.2 Outlet connector

The outlet connector shall be one of the following:

- a) a connector for connection to the manifold;

NOTE Means should be provided to prevent the installation of the incorrect flexible connection, e.g. by the use of gas-specific connections at the manifold (see EN 737-3).

- b) a connector for connection to the inlet port of medical equipment. This connector shall be the cylinder valve outlet for the specific medical gas, in accordance with EN 850, ISO 5145 or the relevant national standard (see ISO/TR 7470 for information).

**5.4.2.1 R** If the outlet connector is in accordance with 5.4.2 b) and EN 850, the length of the body I as shown in Figure 3 shall be 15 mm minimum (see also dimension I of Figure 3 and Table 2 of EN 850:1996).

#### **5.4.3 R Torsion**

Means shall be provided to prevent torsion of the high-pressure flexible connections during connection and disconnection.

Evidence shall be provided by the manufacturer.

#### **5.4.4 Mechanical strength**

High-pressure flexible connections shall be capable of withstanding 2,25 times the working pressure  $P_1$  without permanent deformation.

The test for mechanical strength is given in 6.2.

#### **5.4.5 Leakage**

The maximum external leakage (i.e. leakage to the atmosphere) shall not exceed 0,2 ml/min (0,020 2 kPa l/min) at working pressure  $P_1$ .

This test shall be carried out after the test for mechanical strength.

The test for leakage is given in 6.3.

#### **5.4.6 Bursting pressure**

The bursting pressure of high-pressure flexible connections shall be not less than 3 times the working pressure  $P_1$ .

The test for bursting pressure is given in 6.4.

#### **5.4.7 R Resistance to ignition**

High-pressure flexible connections for all gases shall not ignite when submitted to oxygen pressure shocks.

The test for ignition is given in 6.5.

#### **5.4.8 R Restraining device**

If the high-pressure flexible connection consists of a portion of corrugated metal, means shall be provided to restrain the flexible connection in the event of failure [see Figure 1c)].

Evidence shall be provided by the manufacturer.

### 5.4.9 Pressure drop

The pressure drop across the high-pressure flexible connections shall not exceed the values given in Table 1.

**Table 1 — Requirements for flow and pressure drop**

Intended use	Test pressure kPa	Test flow m <sup>3</sup> /h	Max pressure drop kPa
For cylinders	1 500	5	50
For cylinder bundles	1 500	50	100

## 5.5 Constructional requirements

### 5.5.1 Assembly

**5.5.1.1 R** The methods used to assemble the components of high-pressure flexible connections (e.g. brazing or welding) shall permit the joints to maintain their mechanical characteristics up to an ambient temperature of 450 °C. Filler metals for brazing shall not contain more than a mass fraction of 0,025 % of cadmium.

Evidence shall be provided by the manufacturer.

**5.5.1.2 R** High-pressure flexible connections shall not permit separation of the inlet connector from the outlet connector.

### 5.5.2 R Cleaning

The surfaces of high-pressure flexible connections liable to come in contact with the gas shall be clean and free from oil, grease and particulate matter.

Evidence shall be provided by the manufacturer.

**NOTE 1** Any method of cleaning and degreasing can be used which effectively removes all surface dirt and hydrocarbons, and which leaves no residue itself. Chemical cleaning methods will normally require a subsequent washing and drying process to remove residues.

**NOTE 2** Examples of cleaning procedures will be described in prEN 13159, Compatibility of medical equipment with oxygen, which is in preparation by CEN/TC 215/WG3.