

High-pressure flexible connections for use with medical gases

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National foreword

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Summary of pages

This document comprises a front cover, an inside front cover, the EN title page, pages 2 to 21 and a back cover.

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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).

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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

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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of an identical text or by endorsement, at the latest by August 2000, and conflicting national standards shall be withdrawn at the latest by August 2000.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.

Annexes A and ZA are for information only.

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.

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.

5 General requirements

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.