SLOVENSKI STANDARD
SIST EN 739:2000/A1:2002

01-november-2002

Nizkotlačne povezovalne cevi za delo z medicinskimi plini

Low-pressure hose assemblies for use with medical gases

Niederdruck-Schlauchleitungssysteme zur Verwendung mit medizinischen Gasen

Flexibles de raccordement a basse pression pour utilisation avec les gaz médicaux

Ta slovenski standard je istoveten z: **EN 739:1998/A1:2002**

ICS:

11.040.10	Anestezijska, respiratorna in reanimacijska oprema	Anaesthetic, respiratory and reanimation equipment
83.140.40	Gumene cevi	Hoses

SIST EN 739:2000/A1:2002 **en**

EUROPEAN STANDARD

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ICS 11.040.10; 23.040.70

English version

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Flexibles de raccordement à basse pression pour utilisation avec les gaz médicaux

Niederdruck-Schlauchleitungssysteme zur Verwendung mit medizinischen Gasen

This amendment A1 modifies the European Standard EN 739:1998; it was approved by CEN on 4 March 2002.

CEN members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for inclusion of this amendment into the relevant national standard without any alteration. Up-to-date lists and bibliographical references concerning such national standards may be obtained on application to the Management Centre or to any CEN member.

This amendment 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 Management Centre has the same status as the official versions.

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

EUROPEAN COMMITTEE FOR STANDARDIZATION
COMITÉ EUROPÉEN DE NORMALISATION
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Foreword

This document (EN 739:1998/A1:2002) has been prepared by Technical Committee CEN/TC 215 "Respiratory and anaesthetic equipment", the secretariat of which is held by BSI. It has been prepared so as to accommodate the use of nitric oxide admixed with nitrogen as a medical gas.

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 October 2002, and conflicting national standards shall be withdrawn at the latest by October 2002.

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).

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, Malta, Netherlands, Norway, Portugal, Spain, Sweden, Switzerland and the United Kingdom.

1 Scope

Add to the list of medical gases:

'NO/N_2 mixtures ($NO \leq 1000$ µl/l)'

2 Normative references

'EN 1089-3 Transportable gas cylinders – Cylinder identification – Part 3: Colour coding'

5.3.1

Add a new Note 4:

'NOTE 4 Guidance for the selection of metallic and non-metallic materials for use with NO/N_2 mixtures ($NO \leq 1000$ µl/l) is given in CEN Report CR 13903.'

5.4.1.2

Add the following:

'This clause does not apply to hoses for NO/N_2 mixtures ($NO \leq 1000$ µl/l)'

5.4.5

Amend as follows:

'When tested in accordance with ISO 8033, the adhesion strength shall be at least 1,5 kN/m for both rubber and plastic hoses.'

5.4.8.1

Add the following*:*

'NOTE [1)]: An example of inlet connector suitable for use with NO/N_2 mixtures (NO ≤ 1000 µl/l) is the stem of the quick-connector "Swagelock - QC4 DESO -stainless steel 316".'

Add footnote*:*

'[1)] This information is given for the convenience of users of this standard and does not constitute an endorsement by CEN of the product named.'

5.4.8.2

Add the following*:*

'NOTE [1)]: An example of outlet connector suitable for use with NO/N_2 mixtures(NO ≤ 1000 µl/l) is the body of the quick-connector "Swagelock - QC4 DESO -Stainless steel 316".'

Add footnote:

'[1)] This information is given for the convenience of users of this standard and does not constitute an endorsement by CEN of the product named.'

Add the following new subclause*:*

'**5.4.8.3** Inlet and outlet connectors for NO/N_2 mixtures (NO ≤ 1000 µl/l) shall include a a self-sealing device to minimize leakage into or out of the hose assembly until it is opened by an appropriate connector.'

Add the following new subclause*:*

'5.4.11.3 R The leakage from a hose assembly for NO/N_2 mixtures (NO ≤ 1000 µl/l) when tested at both the inlet and outlet connectors shall not exceed 0,3 ml/min (0,0303 kPa·l/min) during each test.

The test for leakage is given in 6.3.'

5.4.12

Add the following:

'- for NO/N_2 mixtures (NO ≤ 1000 µl/l): 25 kPa at a test pressure of 360 kPa and a test flow of 5 l/min.'

6.1.2

Amend as follows*:*

'Carry out tests with clean, oil-free dry air or nitrogen.

In all cases carry out tests with dry gas with a maximum moisture content of 50 µg/g (50 ppm).'

6.3

Add the following:

'Hose assemblies for NO/N_2 mixtures (NO ≤ 1000 µl/l) shall be tested by applying test pressures of 360 kPa and 800 kPa to each end connector in turn. The leakage shall be measured with the gas supply shut off.'

Table 1

Add the following new row:

'Nitric oxide/nitrogen mixtures (NO ≤ 1000 µl/l); NO/N_2; Black-bright green [7)]

Add Table footnote:

'[7)] according to EN 1089-3'

Annex B

Add the following rationale:

'B.5.4.11.3 The total leakage of 0,3 ml/min is intended to allow for a nominal leakage of 0,2 ml/min at any one end connector and 0,05 ml/min at each hose connection.'

Bibliography

Add 'CEN Report CR 13903:2000, "General guidance on the equipment used for inhaled nitric oxide therapy"

Annex ZA

Add entries showing that subclauses 5.4.8.3 and 5.4.11.3 address Essential Requirement 7.5