Meditsiiniliste gaaside rõhu regulaatorid. Osa 4: Madalrõhuregulaatorid, mis on ette nähtud meditsiinilise aparatuuri koosseisu lülitamiseks

Pressure regulators for use with medical gases - Part 4: Low-pressure regulators intended for incorporation into medical equipment

EESTI STANDARDI EESSÕNA

NATIONAL FOREWORD

Käesolev Eesti standard EVS-EN 738-4:1999 sisaldab Euroopa standardi EN 738-4:1998 ingliskeelset teksti.	This Estonian standard EVS-EN 738-4:1999 consists of the English text of the European standard EN 738-4:1998.
Standard on kinnitatud Eesti Standardikeskuse 23.11.1999 käskkirjaga ja jõustub sellekohase teate avaldamisel EVS Teatajas.	This standard is ratified with the order of Estonian Centre for Standardisation dated 23.11.1999 and is endorsed with the notification published in the official bulletin of the Estonian national standardisation organisation.
Euroopa standardimisorganisatsioonide poolt rahvuslikele liikmetele Euroopa standardi teksti kättesaadavaks tegemise kuupäev on .	Date of Availability of the European standard text .
Standard on kättesaadav Eesti standardiorganisatsioonist.	The standard is available from Estonian standardisation organisation.

ICS 11.040.10

Võtmesõnad: jõudluse hindamine, konstruktsioon, materjalid, meditsiiniaparatuur, meditsiinilised gaasid, mehaaniline tugevus, märgistus, ohutus, pakkimine, rõhuregulaatorid, testimine, utiliseerimine, vooluhulk,

Inglisekeelsed võtmesõnad: design, flow rate, marking, materials, mechanical strength, medical equipment, medical gasses, packing, performance evaluation, pressure regulators, safety, tests, utilization,

EUROPEAN STANDARD
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Descriptors: medical equipment, utilization, medical gases, pressure regulators, safety, materials, design, performance evaluation, flow rate, mechanical strength, tests, marking, packing

English version

Pressure regulators for use with medical gases - Part 4: Low-pressure regulators intended for incorporation into medical equipment

Détendeurs pour l'utilisation avec les gaz médicaux - Partie 4: Détendeurs basse pression conçus pour le matériel médical

Druckminderer zur Verwendung mit medizinischen Gasen - Teil 4: Niederdruckminderer zum Einsetzen in medizinische Geräte

This European Standard was approved by CEN on 2 October 1998.

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

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 April 1999, and conflicting national standards shall be withdrawn at the latest by April 1999.

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.

EN 738 consists of the following parts under the general title "*Pressure regulators for use with medical gases*":

Part 1: *Pressure regulators and pressure regulators with flow-metering devices.*

Part 2: *Manifold and line pressure regulators.*

Part 3: *Pressure regulators integrated with cylinder valves.*

Part 4: *Low-pressure regulators intended for incorporation into medical equipment.*

For special national conditions see annex A.

Annex A forms a normative part of this European Standard. Annexes B, C, D and ZA are given for information only.

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.

Introduction

Pressure regulators are fitted within medical equipment to maintain a constant outlet pressure irrespective of variation of inlet pressure or flow.

To enable correct application of these devices it is important that the operating characteristics are specified and tested in a defined manner.

As pressure regulators of this type are often derived from products designed for industrial applications, this European standard pays particular attention to:

- suitability of materials;
- safety (mechanical strength and resistance to ignition);
- cleanliness;
- testing;
- identification;
- information supplied.

It is also essential that regular inspection and maintenance procedures are recommended.

Clauses and subclauses marked with **R** after their numbers have corresponding rationales contained in annex D.

1 Scope

1.1 This European Standard applies to low-pressure regulators suitable for inlet pressures between 280 kPa and 600 kPa, supplied and packaged as for use in medical equipment intended for the administration of medical gases in the treatment, management, diagnostic evaluation and care of patients for use with the following medical gases:

- oxygen;
- nitrous oxide;
- air for breathing;
- helium;
- carbon dioxide;
- xenon;
- specified mixtures of the gases listed above.

1.2 This European Standard does not apply to pressure regulators supplied as spare parts for a specific application.

1.3 This European Standard does not apply to pressure regulators for use with suction services (see EN ISO 10079-3).

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 737-1	Medical gas pipeline systems - Part 1: Terminal units for compressed medical gases and vacuum
prEN 737-6	Medical gas pipeline systems - Part 6: Dimensions of probes for terminal units for compressed medical gases and vacuum
EN 739	Low-pressure hose assemblies for use with medical gases
EN 1441	Medical devices - Risk analysis