Meditsiiniliste gaaside rõhu regulaatorid. Osa 4: Madalrõhuregulaatorid

Pressure regulators for use with medical gases - Part 4: Low-pressure regulators

EESTI STANDARDI EESSÕNA **NATIONAL FOREWORD**

Käesolev Eesti standard EVS-EN ISO 10524-4:2008 sisaldab Euroopa standardi EN ISO 10524-4:2008 ingliskeelset teksti.	This Estonian standard EVS-EN ISO 10524-4:2008 consists of the English text of the European standard EN ISO 10524-4:2008.
Standard on kinnitatud Eesti Standardikeskuse 21.07.2008 käskkirjaga ja jõustub sellekohase teate avaldamisel EVS Teatajas.	This standard is ratified with the order of Estonian Centre for Standardisation dated 21.07.2008 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 01.06.2008.	Date of Availability of the European standard text 01.06.2008.
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

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Pressure regulators for use with medical gases - Part 4: Low-pressure regulators (ISO 10524-4:2008)

Détendeurs pour l'utilisation avec les gaz médicaux - Partie 4: Détendeurs basse pression (ISO 10524-4:2008)

Druckminderer zur Verwendung mit medizinischen Gasen - Teil 4: Niederdruckminderer (ISO 10524-4:2008)

This European Standard was approved by CEN on 29 May 2008.

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Foreword

This document (EN ISO 10524-4:2008) has been prepared by Technical Committee ISO/TC 121 "Anaesthetic and respiratory equipment" in collaboration with 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of an identical text or by endorsement, at the latest by December 2008, and conflicting national standards shall be withdrawn at the latest by June 2010.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. CEN [and/or CENELEC] shall not be held responsible for identifying any or all such patent rights.

This document supersedes EN 738-4:1998.

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 EC Directive(s).

For relationship with EC Directive(s), see informative Annex ZA, which is an integral part of this document.

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

Endorsement notice

The text of ISO 10524-4:2008 has been approved by CEN as a EN ISO 10524-4:2008 without any modification.

Annex ZA
(informative)

Correspondence between this International Standard and Directive 93/42/EEC

This International Standard has been prepared under a mandate given to CEN by the European Commission and the European Free Trade Association to provide one means of conforming to Essential Requirements of the New Approach Directive 93/42/EEC on Medical devices.

Once this standard is cited in the Official Journal of the European Communities under that Directive and has been implemented as a national standard in at least one Member State, compliance with the clauses of this standard given in Table ZA.1 confers, within the limits of the scope of this standard, a presumption of conformity with the corresponding Essential Requirements of that Directive and associated EFTA regulations.

Table ZA.1 — Correspondence between this International Standard and Directive 93/42/EEC, Medical devices

Clause(s)/Subclause(s) of this International Standard	Essential Requirements (ERs) of EU Directive 93/42/EEC	Qualifying remarks/Notes
5	1	
5.1	2 - 6	
5.1.2	9.1 - 12.7.4	
5.2	2	
5.3	2	
5.3.1	7.1 – 7.3 – 9.3	
5.3.2	7.3 – 9.3	
5.3.3	4 – 7.1 – 9.2	
5.3.4	3 – 5	
5.3.5	7.1 – 7.2	
5.4	2 – 3 – 4	
5.4.1	9.2	
5.4.2.1	10.2 – 10.3	
5.4.2.3	10.2	
5.4.3	9.1 – 12.7.4	
5.4.4	9.1 – 12.7.4	
5.4.6	12.7.1	
5.4.7	7.2 – 7.6	
5.4.8	7.5	
5.4.9	7.5 – 9.2 – 12.7.1	
5.4.10.1	12.8.1 – 12.8.2	
5.4.10.2	10.2	

Clause(s)/Subclause(s) of this International Standard	Essential Requirements (ERs) of EU Directive 93/42/EEC	Qualifying remarks/Notes
5.4.10.3	10.1 – 12.8.1 – 12.8.2	
5.4.10.4	10.1 – 12.8.1 – 12.8.2	
5.4.10.5	12.8.1 – 12.8.2	
5.4.11.1	10.1 – 10.3 – 12.8.1 – 12.8.2	
5.4.11.2	10.1 – 12.8.1 – 12.8.2	
5.4.11.3	10.1 – 12.8.1 – 12.8.2	
5.4.12	10.1 – 12.8.1 – 12.8.2	
5.5.1	7.2 – 9.3	
5.5.2	9.3	
6	7.5 – 9.2 — 9.3 – 12.8.1 – 12.8.2	
7.1	13.1 – 13.2	
7.1.2, 1st dash	13.1	
7.1.2, 2nd dash	13.1	
7.1.2, 3rd dash	13.3 d)	
7.1.4, 1st dash	13.1	
7.1.6	12.9	
7.2	13.2	
7.3	3 - 5	
7.3.1	5 – 7.2 – 7.6	
7.3.3	13.1 – 13.3 b)	
8.1 and 8.2	13.1 – 13.3 a) – 13.4 – 13.6 a)	
8.3	9.1 – 9.3 – 13.6 l)	

WARNING: Other requirements and other EU Directives may be applicable to the product(s) falling within the scope of this standard.

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Introduction

A low-pressure regulator is used to reduce the pressure in a medical gas pipeline system to a lower pressure suitable for use with medical equipment or for delivery of gas directly to a patient.

These functions cover a range of inlet and outlet pressures and flows which require specific design characteristics. It is important that the operating characteristics of low-pressure regulators are appropriately specified for their intended use and then tested in a defined manner.

A low-pressure regulator may be coupled to a device that controls the flow, such as a flow control valve or a fixed orifice. The flow can be indicated by a flowmeter or by a flowgauge.

It is essential that regular inspection and maintenance are undertaken to ensure that low-pressure regulators continue to meet the requirements of this part of ISO 10524.

This part of ISO 10524 pays particular attention to:

— safety (mechanical strength, leakage, safe relief of excess pressure and resistance to ignition);

— suitability of materials;

— gas specificity;

— accuracy;

— cleanliness;

— testing;

— marking;

— information supplied by the manufacturer.

Annex B contains rationale statements for some of the requirements of this part of ISO 10524. The clauses and subclauses marked with an asterisk (*) after their number have corresponding rationale contained in Annex B, included to provide additional insight into the reasoning that led to the requirements and recommendations that have been incorporated in this document. It is considered that knowledge of the reasons for the requirements will not only facilitate the proper application of this part of ISO 10524, but will expedite any subsequent revisions.

Pressure regulators for use with medical gases —

Part 4: Low-pressure regulators

1 Scope

1.1 This part of ISO 10524 applies to the types of low-pressure regulators listed in 1.2 and intended to be used with the following medical gases in the treatment, management, diagnostic evaluation and care of patients:

— oxygen;

— nitrous oxide;

— medical air;

— helium;

— carbon dioxide;

— xenon;

— specified mixtures of the gases listed above;

— air for driving surgical tools;

— nitrogen for driving surgical tools;

— oxygen-enriched air.

1.2 The types of low-pressure regulators covered by this part of ISO 10524 are as follows:

a) low-pressure regulators intended to be connected to terminal units of medical gas pipeline systems complying with ISO 7396-1;

b) low-pressure regulators with integral flow-metering devices intended to be connected to terminal units of medical gas pipeline systems complying with ISO 7396-1;

c) low-pressure regulators intended to be connected to terminal units attached to pressure regulators complying with ISO 10524-1 or ISO 10524-3;

d) operator-adjustable low-pressure regulators for air or nitrogen for driving surgical tools that are an integral part of a medical gas pipeline system complying with ISO 7396-1.

1.3 This part of ISO 10524 does not apply to low-pressure regulators integrated within anaesthetic and respiratory equipment.

2 * Normative references

The following referenced documents are indispensable for the application of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 5359, *Low-pressure hose assemblies for use with medical gases*

ISO 7396-1, *Medical gas pipeline systems — Part 1: Pipeline systems for compressed medical gases and vacuum*

ISO 9170-1, *Terminal units for medical gas pipeline systems — Part 1: Terminal units for use with compressed medical gases and vacuum*

ISO 10524-1, *Pressure regulators for use with medical gases — Part 1: Pressure regulators and pressure regulators with flow-metering devices*

ISO 10524-3, *Pressure regulators for use with medical gases — Part 3: Pressure regulators integrated with cylinder valves*

ISO 11114-3:1997, *Transportable gas cylinders — Compatibility of cylinder and valve materials with gas contents — Part 3: Autogenous ignition test in oxygen atmosphere*

ISO 14971:2007, *Medical devices — Application of risk management to medical devices*

ISO 15001:2003, *Anaesthetic and respiratory equipment — Compatibility with oxygen*

EN 837-1, *Pressure gauges — Part 1: Bourdon tube pressure gauges — Dimensions, metrology, requirements and testing*

EN 1089-3:2004, *Transportable gas cylinders — Gas cylinder identification (excluding LPG) — Part 3: Colour coding*

EN 13544-2, *Respiratory therapy equipment — Part 2: Tubing and connectors*

3 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

3.1
accuracy of flow
difference between the indicated value and the actual value of the flow expressed in percent

3.2
adjustable pressure regulator
pressure regulator that is provided with a means of operator adjustment of the outlet pressure

3.3
flow outlet
outlet intended to deliver a controlled flow of gas

3.4
flowgauge
device that measures pressure and that is calibrated in units of flow

NOTE The flowgauge does not measure flow. It indicates flow by measuring the pressure upstream of a fixed orifice.