SLOVENSKI STANDARD
SIST EN ISO 10524-4:2008

01-september-2008

Nadomeġļa:
SIST EN 738-4:2000

Tlaļ ni regulatorji za medicinske pline - 4. del: Nizkotlaļ ni regulatorji (ISO 10524-4:2008)

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

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

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

Ta slovenski standard je istoveten z: **EN ISO 10524-4:2008**

ICS:

11.040.10	Anestezijska, respiratorna in reanimacijska oprema	Anaesthetic, respiratory and reanimation equipment
23.060.40	Tlaļ ni regulatorji	Pressure regulators

SIST EN ISO 10524-4:2008 **en**

2003-01.Slovenski inštitut za standardizacijo. Razmnoževanje celote ali delov tega standarda ni dovoljeno.

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EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN ISO 10524-4

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ICS 11.040.10

Supersedes EN 738-4:1998

English Version

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)

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Ref. No. EN ISO 10524-4:2008: E

SIST EN ISO 10524-4:2008

Contents

Page

iTeh STANDARD PREVIEW
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SIST EN ISO 10524-4:2008
https://standards.iteh.ai/catalog/standards/sist/b84ed102-9c4d-4a54-9c12-baead5d161d0/sist-en-iso-10524-4-2008

SIST EN ISO 10524-4:2008

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of an identical text or by endorsement, at the latest by December 2008, and conflicting national standards shall be withdrawn at the latest by June 2010.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.

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SIST EN ISO 10524-4:2008
https://standards.iteh.ai/catalog/standards/sist/b84ed102-9c4d-4a54-9c12-baead5d161d0/sist-en-iso-10524-4-2008

Endorsement notice

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

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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	

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(standards.iteh.ai)
SIST EN ISO 10524-4:2008
https://standards.iteh.ai/catalog/standards/sist/b84ed102-9c4d-4a54-9c12-bacad5df61d0/sist-en-iso-10524-4-2008

SIST EN ISO 10524-4:2008

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)	

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(standards.iteh.ai)
SIST EN ISO 10524-4:2008
https://standards.iteh.ai/catalog/standards/sist/b84ed102-9c4d-4a54-9c12-bacad5d161d0/sist-en-iso-10524-4-2008

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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SIST EN ISO 10524-4:2008
https://standards.iteh.ai/catalog/standards/sist/b84ed102-9c4d-4a54-9c12-baead5d161d0/sist-en-iso-10524-4-2008

SIST EN ISO 10524-4:2008

INTERNATIONAL STANDARD

ISO 10524-4

First edition
2008-06-01

Pressure regulators for use with medical gases —

Part 4: Low-pressure regulators

Détendeurs pour l'utilisation avec les gaz médicaux —

Partie 4: Détendeurs basse pression

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(standards.iteh.ai)
SIST EN ISO 10524-4:2008
https://standards.iteh.ai/catalog/standards/sist/b84ed102-9c4d-4a54-9c12-baead5d161d0/sist-en-iso-10524-4-2008

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SIST EN ISO 10524-4:2008

Contents

Page

iTeh STANDARD PREVIEW
(standards.iteh.ai)
SIST EN ISO 10524-4:2008
https://standards.iteh.ai/catalog/standards/sist/b84ed102-0c4d-4a54-9e13-
baead5d161d0/sist-en-iso-10524-4-2008

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Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 2.

The main task of technical committees is to prepare International Standards. Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

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

ISO 10524-4 was prepared by Technical Committee ISO/TC 121, *Anaesthetic and respiratory equipment*, Subcommittee SC 6, *Medical gas systems*.

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ISO 10524 consists of the following parts, under the general title *Pressure regulators for use with medical gases*:

SIST EN ISO 10524-4:2008
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— *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*

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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;

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— gas specificity;

— accuracy;

SIST EN ISO 10524-4:2008
https://standards.iteh.ai/catalog/standards/sist/b84ed102-9c4d-4a54-9c12-baead5d161d0/sist-en-iso-10524-4-2008

— 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.

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