SLOVENSKI STANDARD
SIST EN ISO 10524-2:2019

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Nadomešča:
SIST EN ISO 10524-2:2006

Tlačni regulatorji za medicinske pline - 2. del: Tlačni regulatorji v razdelilnikih in ceveh (ISO 10524-2:2018)

Pressure regulators for use with medical gases - Part 2: Manifold and line pressure regulators (ISO 10524-2:2018)

Druckminderer zur Verwendung mit medizinischen Gasen - Teil 2: Hauptstellendruckregler und Leitungsdruckminderer (ISO 10524-2:2018)

Détendeurs pour l'utilisation avec les gaz médicaux - Partie 2: Détendeurs de rampes et de canalisations (ISO 10524-2:2018)

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ICS:

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

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English Version

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This European Standard was approved by CEN on 13 December 2018.

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EUROPEAN COMMITTEE FOR STANDARDIZATION
COMITÉ EUROPÉEN DE NORMALISATION
EUROPÄISCHES KOMITEE FÜR NORMUNG

CEN-CENELEC Management Centre: Rue de la Science 23, B-1040 Brussels

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European foreword

This document (EN ISO 10524-2:2019) 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of an identical text or by endorsement, at the latest by July 2019, and conflicting national standards shall be withdrawn at the latest by July 2019.

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

This document supersedes EN ISO 10524-2:2006.

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, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, Former Yugoslav Republic of Macedonia, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Serbia, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and the United Kingdom.

Endorsement notice

The text of ISO 10524-2:2018 has been approved by CEN as EN ISO 10524-2:2019 without any modification.

INTERNATIONAL STANDARD

ISO 10524-2

Second edition
2018-01

Pressure regulators for use with medical gases —

Part 2: Manifold and line pressure regulators

Détendeurs pour l'utilisation avec les gaz médicaux —

Partie 2: Détendeurs de rampes et de canalisations

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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.

The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular the different approval criteria needed for the different types of ISO documents should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see www.iso.org/directives).

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. Details of any patent rights identified during the development of the document will be in the Introduction and/or on the ISO list of patent declarations received (see www.iso.org/patents).

Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

For an explanation on the voluntary nature of standards, the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT) see the following URL: www.iso.org/iso/foreword.html.

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

This second edition cancels and replaces the first edition (ISO 10524-2:2005), which has been technically revised.

The main changes compared to the previous edition are as follows:

— the scope has been extended to include 30 000 kPa (300 bar) manifold pressure regulators;

— this document has been restructured according to the new ISO template and associated renumbering;

— the common requirements have been aligned with ISO 10524-1 and ISO 10524-3;

— all type tests have been reviewed;

— a complete schedule has been introduced;

— a pressure retention test of the low-pressure side for the line pressure regulators has been introduced.

A list of all parts in the ISO 10524 series can be found on the ISO website.

Introduction

MANIFOLD PRESSURE REGULATORS are used within the supply systems of medical gas pipeline systems to reduce high cylinder pressure to a lower pressure suitable for the supply of medical gases to the inlet of LINE PRESSURE REGULATORS.

LINE PRESSURE REGULATORS are used to reduce the pressure supplied by MANIFOLD PRESSURE REGULATORS or by cryogenic vessels to the lower pressure required at the terminal units of MEDICAL GAS PIPELINE SYSTEMS.

These functions cover a wide range of inlet and outlet pressures and flows which require specific design characteristics. It is important that the operating characteristics of MANIFOLD and LINE PRESSURE REGULATORS are specified and tested in a defined manner.

It is essential that regular inspection and maintenance be undertaken to ensure that the PRESSURE REGULATORS continue to meet the requirements of this document.

This document pays particular attention to

— use of suitable materials,

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

— cleanliness,

— type testing,

— marking, and

— information supplied by the manufacturer.

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

An asterisk (*) as the first character of a title or at the beginning of a paragraph or table title indicates that there is guidance or rationale related to that item in Annex B.

In this document, the following print types are used:

— requirements and definitions: roman type.

— informative material appearing outside of tables, such as notes, examples and references: in smaller type. Normative text of tables is also in a smaller type;

— *test specifications: italic type*;

— TERMS DEFINED IN CLAUSE 3 OF THIS DOCUMENT OR AS NOTED: SMALL CAPITALS TYPE.

Pressure regulators for use with medical gases —

Part 2:
Manifold and line pressure regulators

1 * Scope

This document specifies design, construction, type testing, and marking requirements for MANIFOLD PRESSURE REGULATORS (as defined in 3.7) and LINE PRESSURE REGULATORS (as defined in 3.5) intended for use in MEDICAL GAS PIPELINE SYSTEMS.

Examples of gases include oxygen, medical air and oxygen/nitrous oxide mixtures.

This document applies to MANIFOLD PRESSURE REGULATORS and LINE PRESSURE REGULATORS supplied as individual units or to the relevant components incorporated within an assembly.

MANIFOLD PRESSURE REGULATORS are intended to be connected to a MANIFOLD system which has a NOMINAL INLET PRESSURE, P_1 of up to 30 000 kPa (300 bar).

LINE PRESSURE REGULATORS are intended to be connected downstream of the MANIFOLD PRESSURE REGULATOR with a supply pressure up to 3 000 kPa (30 bar).

This document does not apply to PRESSURE REGULATORS for use with vacuum pipeline systems.

NOTE Requirements for PRESSURE REGULATORS for use with vacuum pipeline systems are covered in ISO 10079-3.

2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements 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 32, *Gas cylinders for medical use — Marking for identification of content*

ISO 7000, *Graphical symbols for use on equipment — Registered symbols*

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

ISO 10297:2014, *Gas cylinders — Cylinder valves — Specification and type testing*

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

ISO 15001:2010, *Anaesthetic and respiratory equipment — Compatibility with oxygen*

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

IEC 60601-1, *Medical electrical equipment — Part 1: General requirements for basic safety and essential performance*

3 Terms and definitions

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