This is a free page sample. Access the full version online.

NSAI Standards

Irish Standard
I.S. EN ISO 10524-2:2019

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

© CEN 2019 No copying without NSAI permission except as permitted by copyright law.

This is a free page sample. Access the full version online.

I.S. EN ISO 10524-2:2019

Incorporating amendments/corrigenda/National Annexes issued since publication:

The National Standards Authority of Ireland (NSAI) produces the following categories of formal documents:

I.S. xxx: Irish Standard — national specification based on the consensus of an expert panel and subject to public consultation.

S.R. xxx: Standard Recommendation — recommendation based on the consensus of an expert panel and subject to public consultation.

SWiFT xxx: A rapidly developed recommendatory document based on the consensus of the participants of an NSAI workshop.

This document replaces/revises/consolidates the NSAI adoption of the document(s) indicated on the CEN/CENELEC cover/Foreword and the following National document(s):

NOTE: The date of any NSAI previous adoption may not match the date of its original CEN/CENELEC document.

This document is based on:	*Published:*
EN ISO 10524-2:2019	2019-01-30

This document was published under the authority of the NSAI and comes into effect on:	ICS number:
2019-02-17	11.040.10
	NOTE: If blank see CEN/CENELEC cover page

NSAI	T +353 1 807 3800	Sales:
1 Swift Square,	F +353 1 807 3838	T +353 1 857 6730
Northwood, Santry	E standards@nsai.ie	F +353 1 857 6729
Dublin 9	W NSAI.ie	W standards.ie

Údarás um Chaighdeáin Náisiúnta na hÉireann

This is a free page sample. Access the full version online.

National Foreword

I.S. EN ISO 10524-2:2019 is the adopted Irish version of the European Document EN ISO 10524-2:2019, Pressure regulators for use with medical gases - Part 2: Manifold and line pressure regulators (ISO 10524-2:2018)

This document does not purport to include all the necessary provisions of a contract. Users are responsible for its correct application.

For relationships with other publications refer to the NSAI web store.

Compliance with this document does not of itself confer immunity from legal obligations.

In line with international standards practice the decimal point is shown as a comma (,) throughout this document.

This is a free page sample. Access the full version online.

This page is intentionally left blank

This is a free page sample. Access the full version online.

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN ISO 10524-2

January 2019

ICS 11.040.10

Supersedes EN ISO 10524-2:2006

English Version

Pressure regulators for use with medical gases - Part 2: Manifold and line pressure regulators (ISO 10524-2:2019)

Détendeurs pour l'utilisation avec les gaz médicaux - Partie 2: Détendeurs de rampes et de canalisations (ISO 10524-2:2019)

Druckminderer zur Verwendung mit medizinischen Gasen - Teil 2: Hauptstellendruckregler und Leitungsdruckminderer (ISO 10524-2:2019)

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

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 CEN-CENELEC Management Centre 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 CEN-CENELEC Management Centre has the same status as the official versions.

CEN members are the national standards bodies of 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 United Kingdom.

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

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

© 2019 CEN All rights of exploitation in any form and by any means reserved worldwide for CEN national Members.

Ref. No. EN ISO 10524-2:2019 E

This is a free page sample. Access the full version online.

Contents

Page

European foreword **3**

This is a free page sample. Access the full version online.

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.

This is a free page sample. Access the full version online.

This page is intentionally left blank

This is a free page sample. Access the full version online.

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

Reference number
ISO 10524-2:2018(E)

© ISO 2018

This is a free page sample. Access the full version online.

COPYRIGHT PROTECTED DOCUMENT

© ISO 2018

All rights reserved. Unless otherwise specified, or required in the context of its implementation, no part of this publication may be reproduced or utilized otherwise in any form or by any means, electronic or mechanical, including photocopying, or posting on the internet or an intranet, without prior written permission. Permission can be requested from either ISO at the address below or ISO's member body in the country of the requester.

ISO copyright office
CP 401 • Ch. de Blandonnet 8
CH-1214 Vernier, Geneva, Switzerland
Tel. +41 22 749 01 11
Fax +41 22 749 09 47
copyright@iso.org
www.iso.org

Published in Switzerland

This is a free page sample. Access the full version online.

Contents

Page

Foreword ..... **v**

Introduction ..... **vi**

1 * Scope **1**

2 Normative references **1**

3 Terms and definitions **1**

4 Nomenclature **4**

5 General requirements **4**
- 5.1 Safety 4
- 5.2 Usability 4
- 5.3 Alternative construction 4
- 5.4 Materials 5

6 Design requirements **6**
- 6.1 General 6
- 6.2 Pressure gauges 6
- 6.3 Integrated digital gauges 6
- 6.4 Pressure-adjusting device 6
- 6.5 Filtration 7
- 6.6 Mechanical strength 7
  - 6.6.1 Resistance of the high-pressure side 7
  - 6.6.2 Resistance of the low-pressure side to pneumatic pressure 7
  - 6.6.3 Resistance of the low pressure side to P_1 7
- 6.7 Endurance 7
- 6.8 Manifold pressure regulators 8
  - 6.8.1 * Inlet connector 8
  - 6.8.2 Outlet connector 8
  - 6.8.3 Leakage 8
  - 6.8.4 Functional and flow characteristics 8
  - 6.8.5 Pressure-relief device 9
  - 6.8.6 * Resistance to ignition 9
  - 6.8.7 Nominal inlet pressure 9
- 6.9 Line pressure regulators 9
  - 6.9.1 * Inlet connector 9
  - 6.9.2 Outlet connector 9
  - 6.9.3 Leakage 9
  - 6.9.4 Outlet pressure variation limits 10
  - 6.9.5 * Resistance to ignition of sealing materials and lubricants 10
  - 6.9.6 Nominal inlet pressure 10

7 Construction requirements **10**
- 7.1 * Cleanliness 10
- 7.2 Lubricants 10

8 Test methods for type tests **11**
- 8.1 General conditions 11
  - 8.1.1 General 11
  - 8.1.2 Ambient conditions 11
  - 8.1.3 Test gas 11
  - 8.1.4 Reference conditions 11
- 8.2 Test schedule 11
- 8.3 Test methods for manifold pressure regulators 13
  - 8.3.1 Test equipment for functional and flow characteristics 13
  - 8.3.2 Test method for determining standard discharge, Q_1 13
  - 8.3.3 Test method for determining the coefficient of pressure increase upon closure 14

© ISO 2018 – All rights reserved

This is a free page sample. Access the full version online.

8.3.4 Test method for determining the irregularity coefficient ... 15
8.3.5 Test method for PRESSURE-RELIEF DEVICE ... 17
8.3.6 Test methods for leakage ... 17
8.3.7 Test method for mechanical strength ... 18
8.3.8 Test method for resistance to ignition ... 18
8.4 Test method for LINE PRESSURE REGULATORS ... 19
8.4.1 Test method for measuring the variation of the outlet pressure ... 19
8.4.2 Test methods for leakage ... 19
8.4.3 Test method for mechanical strength ... 20
8.4.4 Test method for determination of the auto-ignition temperature of sealing materials and lubricants ... 20
8.5 Endurance test ... 22
8.6 Test method for durability of markings and colour coding ... 23

9 Marking, colour coding, and packaging ... 23
9.1 Marking ... 23
9.2 Colour coding ... 24
9.3 Packaging ... 24

10 Information to be supplied by the manufacturer ... 24

Annex A (informative) **Examples of PRESSURE REGULATORS ... 26**

Annex B (informative) **Rationale ... 27**

Annex C (informative) **Reported regional and national deviations of colour coding and nomenclature for medical gases ... 29**

Bibliography ... 31

 © ISO 2018 – All rights reserved

This is a free page sample. Access the full version online.

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.

© ISO 2018 – All rights reserved

This is a free page sample. Access the full version online.

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.

© ISO 2018 – All rights reserved

This is a free page sample. Access the full version online.

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.

© ISO 2018 – All rights reserved

SAI GLOBAL

This is a free preview. Purchase the entire publication at the link below:

Product Page

Looking for additional Standards? Visit Intertek Inform Infostore

Learn about LexConnect, All Jurisdictions, Standards referenced in Australian legislation