



NSAI
Standards

Irish Standard
I.S. EN ISO 10524-1:2019

Pressure regulators for use with medical gases - Part 1: Pressure regulators and pressure regulators with flow-metering devices (ISO 10524-1:2018)

I.S. EN ISO 10524-1:2019

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NSAI
1 Swift Square,
Northwood, Santry
Dublin 9

T +353 1 807 3800
F +353 1 807 3838
E standards@nsai.ie
W NSAI.ie

Sales:
T +353 1 857 6730
F +353 1 857 6729
W standards.ie

Údarás um Chaighdeáin Náisiúnta na hÉireann

National Foreword

I.S. EN ISO 10524-1:2019 is the adopted Irish version of the European Document EN ISO 10524-1:2019, Pressure regulators for use with medical gases - Part 1: Pressure regulators and pressure regulators with flow-metering devices (ISO 10524-1:2018)

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EUROPEAN STANDARD

EN ISO 10524-1

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English Version

Pressure regulators for use with medical gases - Part 1:
Pressure regulators and pressure regulators with flow-
metering devices (ISO 10524-1:2018)

Détendeurs pour l'utilisation avec les gaz médicaux-
Partie 1: Détendeurs et détendeurs-débitmètres (ISO
10524-1:2018)

Druckminderer zur Verwendung mit medizinischen
Gasen - Teil 1: Druckminderer und Druckminderer mit
Durchflussmessgeräten (ISO 10524-1:2018)

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

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

EN ISO 10524-1:2019 (E)

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European foreword

This document (EN ISO 10524-1:2019) 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of an identical text or by endorsement, at the latest by July 2019, and conflicting national standards shall be withdrawn at the latest by July 2019.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.

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Endorsement notice

The text of ISO 10524-1:2018 has been approved by CEN as EN ISO 10524-1:2019 without any modification.

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**INTERNATIONAL
STANDARD**

**ISO
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**Pressure regulators for use with
medical gases —**

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

Détendeurs pour l'utilisation avec les gaz médicaux —

Partie 1: Détendeurs et détendeurs-débitmètres



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

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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 10524-1:2006), which has been technically revised.

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

- the common requirements have been aligned with ISO 10524-2 and ISO 10524-3;
- this document has been restructured according to the new ISO template and associated renumbering;
- a complete schedule has been introduced;
- all type tests have been reviewed.

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

ISO 10524-1:2018(E)

Introduction

PRESSURE REGULATORS are used to reduce high cylinder pressure to a lower pressure suitable for use with medical equipment or for delivery of gas directly to a patient.

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 PRESSURE REGULATORS are specified and tested in a defined manner.

A PRESSURE REGULATOR normally has coupled to it a device which controls the flow, such as a flow control device or a fixed ORIFICE. The flow can be indicated by a FLOWMETER or by a FLOWGAUGE.

It is essential that regular inspection and maintenance be undertaken to ensure that the PRESSURE REGULATOR continues 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),
- GAS SPECIFICity,
- cleanliness,
- type testing,
- marking, and
- information supplied by the manufacturer.

[Annex A](#) 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 A](#).

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 1:

Pressure regulators and pressure regulators with flow-metering devices

1 Scope

This document specifies the design, construction, type testing, and marking requirements for PRESSURE REGULATORS (as defined in 3.18) intended for the administration of medical gases and their mixtures in the treatment, management, diagnostic evaluation and care of patients or for gases used for driving surgical tools.

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

This document applies to PRESSURE REGULATORS:

- a) intended to be connected to cylinders by the operator;
- b) with integral flow-metering devices intended to be connected to cylinders by the operator;
- c) that are an integral part of medical equipment (e.g. anaesthetic workstations, lung ventilators, resuscitators).

A PRESSURE REGULATOR can be provided with PRESSURE OUTLET or FLOW OUTLET, and can be adjustable or pre-set.

PRESSURE REGULATORS are intended to be fitted to refillable cylinders with a WORKING PRESSURE up to 30 000 kPa (300 bar) and can be provided with devices which control and measure the flow of the medical gas delivered.

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 407, *Small medical gas cylinders — Pin-index yoke-type valve connections*

ISO 5145, *Cylinder valve outlets for gases and gas mixtures — Selection and dimensioning*

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

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

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