ICS 11.040.10 SLOVENSKÁ TECHNICKÁ NORMA Október 2025

STN	**Potrubné systémy medicinálnych plynov Časť 3: Dávkovacie jednotky na výrobu syntetického medicinálneho vzduchu (ISO 7396-3: 2025)**	**STN EN ISO 7396-3** 85 2751

Medical gas pipeline systems - Part 3:Proportioning units for the production of synthetic medical air (ISO 7396-3:2025)

Táto norma obsahuje anglickú verziu európskej normy.
This standard includes the English version of the European Standard.

Táto norma bola oznámená vo Vestníku ÚNMS SR č. 09/25

Obsahuje: EN ISO 7396-3:2025, ISO 7396-3:2025

141125

EUROPEAN STANDARD
NORME EUROPÉENNE
EUROPÄISCHE NORM

EN ISO 7396-3

July 2025

ICS 11.040.10

English Version

Medical gas pipeline systems - Part 3:Proportioning units for the production of synthetic medical air (ISO 7396-3:2025)

Systèmes de distribution de gaz médicaux - Partie 3: Unités mélangeurs pour la production d'air médical reconstitué (ISO 7396-3:2025)

Rohrleitungssysteme für medizinische Gase - Teil 3: Gasmischersysteme für die Herstellung von synthetischer medizinischer Luft (ISO 7396-3:2025)

This European Standard was approved by CEN on 28 June 2025.

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, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Republic of North Macedonia, Romania, Serbia, Slovakia, Slovenia, Spain, Sweden, Switzerland, Türkiye 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

Ref. No. EN ISO 7396-3:2025 E

Contents

Page

European foreword

This document (EN ISO 7396-3:2025) 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 January 2026, and conflicting national standards shall be withdrawn at the latest by January 2026.

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.

Any feedback and questions on this document should be directed to the users’ national standards body/national committee. A complete listing of these bodies can be found on the CEN website.

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, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Republic of North Macedonia, Romania, Serbia, Slovakia, Slovenia, Spain, Sweden, Switzerland, Türkiye and the United Kingdom.

Endorsement notice

The text of ISO 7396-3:2025 has been approved by CEN as EN ISO 7396-3:2025 without any modification.

International Standard

ISO 7396-3

First edition
2025-07

Medical gas pipeline systems —

Part 3: Proportioning units for the production of synthetic medical air

Systèmes de distribution de gaz médicaux —

Partie 3: Unités mélangeurs pour la production d'air médical reconstitué

Reference number
ISO 7396-3:2025(en)

ISO copyright office
CP 401 • Ch. de Blandonnet 8
CH-1214 Vernier, Geneva
Phone: +41 22 749 01 11
Email: copyright@iso.org
Website: www.iso.org

Published in Switzerland

Contents

Page

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 document 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).

ISO draws attention to the possibility that the implementation of this document may involve the use of (a) patent(s). ISO takes no position concerning the evidence, validity or applicability of any claimed patent rights in respect thereof. As of the date of publication of this document, ISO had not received notice of (a) patent(s) which may be required to implement this document. However, implementers are cautioned that this may not represent the latest information, which may be obtained from the patent database available at www.iso.org/patents. ISO shall not be held responsible for identifying any or all such patent rights.

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

For an explanation of 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 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 supply systems,* in collaboration with the European Committee for Standardization (CEN) Technical Committee CEN/TC 215, *Respiratory and anaesthetic equipment,* in accordance with the Agreement on technical cooperation between ISO and CEN (Vienna Agreement).

Any feedback or questions on this document should be directed to the user's national standards body. A complete listing of these bodies can be found at www.iso.org/members.html.

Introduction

Proportioning units are components of a supply system intended to supply synthetic medical air to a medical gas pipeline distribution system complying with ISO 7396-1.

ISO 7396-1 requires that a supply system consists of at least three sources of supply which can typically be, in addition to a proportioning unit, cylinder manifolds with associated pressure regulators.

The selection of the components to be associated to a proportioning unit within the supply system, included the reservoir, is therefore the responsibility of the manufacturer of the pipeline system.

When a proportioning unit is used as primary source of supply, the other sources of supply are used as the secondary and/or reserve source to supply the pipeline distribution system in the event of failure of the proportioning unit.

This document pays particular attention to:

— use of suitable materials;

— safety (mechanical strength, leakage, safe relief of excess pressure);

— compliance of the product gas with specification;

— monitoring of the production process;

— cleanliness;

— testing;

— marking;

— packaging;

— information supplied by the manufacturer.

Annex C contains rationale statements for some of the requirements of this document.

NOTE Synthetic medical air is referred to as “air, synthetic medicinal” in the most current European Pharmacopoeia monograph.

International Standard **ISO 7396-3:2025(en)**

Medical gas pipeline systems —

Part 3:
Proportioning units for the production of synthetic medical air

1 Scope

1.1 This document specifies requirements relating to the construction and operation of devices producing air through the blending of oxygen and nitrogen for use as sources of supply in supply systems for medical gases.

1.2 This document is applicable to proportioning units intended to produce synthetic medical air and air for driving surgical tools by mixing in defined proportions oxygen and nitrogen.

1.3 This document is applicable to proportioning units intended to be components of a medical gas supply system for medical air which supplies a medical gas pipeline distribution system complying with ISO 7396-1.

1.4 The number of proportioning units within the medical air supply system and their combination with other sources of supply (e.g. cylinder manifolds) to ensure that the supply system consists of at least three sources of supply is outside the scope of this document.

Requirements for the supply systems for medical air are given in ISO 7396-1.

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 4126-1, *Safety devices for protection against excessive pressure — Part 1: Safety valves*

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

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

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

ISO 20417, *Information to be supplied by the manufacturer*

IEC 60204-1, *Safety of machinery - Electrical equipment of machines – Part 1: General requirements*

IEC 60529, *Degrees of protection provided by enclosures (IP Code)*

IEC 61000-6-2, *Electromagnetic compatibility (EMC) – Part 6-2: Generic standards - Immunity standard for industrial environments*

IEC 61000-6-4, *Electromagnetic compatibility (EMC) – Part 6-4: Generic standards - Emission standard for industrial environments*

IEC 61439-1, *Low-voltage switchgear and control gear assemblies - Part 1: General rules*

IEC 62304, *Medical device software — Software life cycle processes*