

SLOVENSKI STANDARD SIST EN ISO 15002:2024

01-junij-2024

Nadomešča:

SIST EN ISO 15002:2008/A1:2020

Naprave za uravnavanje pretoka v priključitvi na sistem oskrbe z medicinskimi plini (ISO 15002:2023)

Flow control devices for connection to a medical gas supply system (ISO 15002:2023)

Durchflussregeleinrichtungen zum Anschluss an ein Versorgungssystem für medizinische Gase (ISO 15002:2023)

Dispositifs de contrôle du débit pour raccordement à un système d'alimentation en gaz médicaux (ISO 15002:2023)

Ta slovenski standard je istoveten z: EN ISO 15002:2024

ICS:

11.040.10 Anestezijska, respiratorna in Anaesthetic, respiratory and

reanimacijska oprema reanimation equipment

SIST EN ISO 15002:2024 en,fr,de

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EUROPEAN STANDARD NORME EUROPÉENNE EUROPÄISCHE NORM

EN ISO 15002

March 2024

ICS 11.040.10

Supersedes EN ISO 15002:2008

English Version

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Durchflussregeleinrichtungen zum Anschluss an ein Versorgungssystem für medizinische Gase (ISO 15002:2023)

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

EN ISO 15002:2024 (E)

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SIST EN ISO 15002:2024

European foreword

The text of ISO 15002:2023 has been prepared by Technical Committee ISO/TC 121 "Anaesthetic and respiratory equipment" of the International Organization for Standardization (ISO) and has been taken over as EN ISO 15002:2024 by 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of an identical text or by endorsement, at the latest by September 2024, and conflicting national standards shall be withdrawn at the latest by September 2024.

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INTERNATIONAL STANDARD

ISO 15002

Third edition 2023-08

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Dispositifs de contrôle du débit pour raccordement à un système d'alimentation en gaz médicaux

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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 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).

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

This third edition cancels and replaces the second edition (ISO 15002:2008), which has been technically revised. It also incorporates the Amendment ISO 15002:2008/Amd.1:2018.

The main changes are as follows:

- title changed as the requirements for *flow control devices* are the same regardless of the gas supply and they control the flow, they do not measure the flow;
- layout changed from requirements for each type of flow control device to the common requirements
 as they are the same for each flow control device;
- test methods have been rationalised and put into a new <u>Annex C;</u>
- hazard identification list added as a new <u>Annex D</u>;
- the maximum flow that can be achieved when the flow control is opened fully has been included as a marking requirement on the device so that the user will know what could be delivered to the patient. A rationale has also been added to cover this marking requirement;
- a new requirement has been added for stability of setting;
- the environmental conditions have been aligned with IEC 60601-1-12, emergency equipment, as *flow control devices* are used in such environments; and
- the requirement for accuracy has been rationalised for clarity.

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