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STN	**Infúzne prístroje používané v zdravotníctve Časť 13: Odstupňované regulátory prietoku na jednorazové použitie s infúznymi súpravami (ISO 8536-13: 2024)**	**STN EN ISO 8536-13** 70 3350

Infusion equipment for medical use - Part 13: Graduated flow regulators for single use with fluid contact (ISO 8536-13:2024)

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. 12/24

Obsahuje: EN ISO 8536-13:2024, ISO 8536-13:2024

Oznámením tejto normy sa ruší
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EUROPEAN STANDARD
NORME EUROPÉENNE
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EN ISO 8536-13

September 2024

ICS 11.040.20

Supersedes EN ISO 8536-13:2016

English Version

Infusion equipment for medical use - Part 13: Graduated flow regulators for single use with fluid contact (ISO 8536-13:2024)

Matériel de perfusion à usage médical - Partie 13: Régulateurs de débit gradués non réutilisables avec contact à fluide (ISO 8536-13:2024)

Infusionsgeräte zur medizinischen Verwendung - Teil 13: Graduierte Durchflussregler zur einmaligen Verwendung mit Flüssigkeitskontakt (ISO 8536-13:2024)

This European Standard was approved by CEN on 20 September 2024.

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

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Ref. No. EN ISO 8536-13:2024 E

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European foreword

This document (EN ISO 8536-13:2024) has been prepared by Technical Committee ISO/TC 76 "Transfusion, infusion and injection, and blood processing equipment for medical and pharmaceutical use" in collaboration with Technical Committee CEN/TC 205 “Non-active medical devices” the secretariat of which is held by DIN.

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of an identical text or by endorsement, at the latest by March 2025, and conflicting national standards shall be withdrawn at the latest by March 2025.

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 8536-13:2024 has been approved by CEN as EN ISO 8536-13:2024 without any modification.

International Standard

ISO 8536-13

Infusion equipment for medical use —

Part 13: Graduated flow regulators for single use with fluid contact

Matériel de perfusion à usage médical —

Partie 13: Régulateurs de débit gradués non réutilisables avec contact à fluide

Second edition
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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).

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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 76, *Transfusion, infusion and injection, and blood processing equipment for medical and pharmaceutical use,* in collaboration with the European Committee for Standardization (CEN) Technical Committee CEN/TC 205, *Non-active medical devices,* in accordance with the Agreement on technical cooperation between ISO and CEN (Vienna Agreement).

This second edition cancels and replaces the first edition (ISO 8536-13:2016), which has been technically revised.

The main changes are as follows:

— in Clause 3, the new term “activation” has been added;

— Figure 1 in Clause 4 has been amended to include markings on the open and close positions;

— former Clause 8 “Biological requirements” has been deleted due to the specified product being non-sterile;

— Annex A has been amended by a general introduction (see A.1) on the pre-conditioning of the sample;

— Annex A.5 has been amended to align the flow rate test method with other flow rate test methods in the ISO 8536 series;

— the Bibliography has been updated.

A list of all parts in the ISO 8536 series can be found on the ISO website.

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.

International Standard **ISO 8536-13:2024(en)**

Infusion equipment for medical use —

Part 13:
Graduated flow regulators for single use with fluid contact

1 Scope

This document specifies requirements for non-sterile, single-use graduated flow regulators used as subcomponents in sterilized infusion sets for single use to control the flow of intravenous infusion solutions with fluid contact under gravity feed conditions.

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 8536-4, *Infusion equipment for medical use — Part 4: Infusion sets for single use, gravity feed*

ISO 10993-1, *Biological evaluation of medical devices — Part 1: Evaluation and testing within a risk management process*

ISO 80000-4, *Quantities and units — Part 4: Mechanics*