



# SLOVENSKI STANDARD

## oSIST prEN ISO 8536-13:2023

01-november-2023

Nadomešča:

SIST EN ISO 8536-13:2017

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**Infuzijska oprema za uporabo v medicini - 13. del: Regulatorji graduiranega pretoka za enkratno uporabo pri stiku s tekočino (ISO/DIS 8536-13:2023)**

Infusion equipment for medical use - Part 13: Graduated flow regulators for single use with fluid contact (ISO/DIS 8536-13:2023)

Infusionsgeräte zur medizinischen Verwendung - Teil 13: Graduierte Durchflussregler zur einmaligen Verwendung mit Flüssigkeitskontakt (ISO/DIS 8536-13:2023)

Matériel de perfusion à usage médical - Partie 13: Régulateurs de débit gradués non réutilisables avec contact à fluide (ISO/DIS 8536-13:2023)

**Ta slovenski standard je istoveten z: prEN ISO 8536-13**

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**ICS:**

11.040.20	Transfuzijska, infuzijska in injekcijska oprema	Transfusion, infusion and injection equipment
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**oSIST prEN ISO 8536-13:2023**

**en,fr,de**



# DRAFT INTERNATIONAL STANDARD

## ISO/DIS 8536-13

ISO/TC 76

Secretariat: DIN

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2023-11-14

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## 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*

ICS: 11.040.20

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<b>Contents</b>	<b>Page</b>
<b>Foreword</b> .....	<b>iv</b>
<b>1 Scope</b> .....	<b>1</b>
<b>2 Normative references</b> .....	<b>1</b>
<b>3 Terms and definitions</b> .....	<b>1</b>
<b>4 Design</b> .....	<b>2</b>
<b>5 Materials</b> .....	<b>2</b>
<b>6 Physical requirements</b> .....	<b>2</b>
6.1 Graduated scale.....	2
6.2 Particulate contamination.....	2
6.3 Tensile strength.....	3
6.4 Leakage.....	3
6.5 Flow rates.....	3
<b>7 Chemical requirements</b> .....	<b>3</b>
<b>Annex A (informative) Physical tests</b> .....	<b>4</b>
<b>Bibliography</b> .....	<b>6</b>

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## ISO/DIS 8536-13:2023(E)

### Foreword

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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 of ISO 8536-13 cancels and replaces the first edition (ISO 8536-13:2016), which has been technically revised with the following changes:

- in [Clause 3](#) the new term “activation” has been added;
- [Clause 4](#) “Design” has been amended and includes now a Figure with markings on the open and close positions;
- former Clause “Biological requirements” has been deleted due to that the specified product is non-sterile;
- [Annex A](#) “Physical test” has been amended by a general introduction on the pre-conditioning of the sample.
- Bibliography has been updated;
- some minor editorial changes were introduced in the whole document.

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](http://www.iso.org/members.html).