

SLOVENSKI STANDARD SIST EN ISO 8536-4:2020

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Nadomešča:

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Infuzijska oprema za uporabo v medicini - 4. del: Infuzijski seti za enkratno uporabo, delujoči na osnovi gravitacije (ISO 8536-4:2019)

Infusion equipment for medical use - Part 4: Infusion sets for single use, gravity feed (ISO 8536-4:2019)

Infusionsgeräte zur medizinischen Verwendung - Teil 4: Infusionsgeräte für Schwerkraftinfusionen zur einmaligen Verwendung (ISO 8536-4:2019)

Matériel de perfusion à usage médical - Partie 4: Appareils de perfusion non réutilisables, à alimentation par gravité (ISO 8536-4:2019)

Ta slovenski standard je istoveten z: EN ISO 8536-4:2020

ICS:

11.040.20	Transfuzijska, infuzijska in injekcijska oprema	Transfusion, infusion and injection equipment
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SIST EN ISO 8536-4:2020

en

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Supersedes EN ISO 8536-4:2013

English Version

Infusion equipment for medical use - Part 4: Infusion sets for single use, gravity feed (ISO 8536-4:2019)

Matériel de perfusion à usage médical - Partie 4:
Appareils de perfusion non réutilisables, à
alimentation par gravité (ISO 8536-4:2019)

Infusionsgeräte zur medizinischen Verwendung - Teil
4: Infusionsgeräte für Schwerkraftinfusionen zur
einmaligen Verwendung (ISO 8536-4:2019)

This European Standard was approved by CEN on 17 October 2019.

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European foreword

This document (EN ISO 8536-4:2020) 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of an identical text or by endorsement, at the latest by July 2020, and conflicting national standards shall be withdrawn at the latest by January 2023.

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.

This document supersedes EN ISO 8536-4:2013.

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INTERNATIONAL
STANDARD

ISO
8536-4

Sixth edition
2019-09

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

Matériel de perfusion à usage médical —

*Partie 4: Appareils de perfusion non réutilisables, à alimentation
par gravité*

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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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This document was prepared by Technical Committee ISO/TC 76, *Transfusion, infusion and injection, and blood processing equipment for medical and pharmaceutical use*.

This sixth edition cancels and replaces the fifth edition (ISO 8536-4:2010), which has been technically revised. It also incorporates the Amendment ISO 8536-4:2010/Amd.1:2013.

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

- [Clause 5](#) 'Designation' now refers to [Clause 10](#) 'Labelling';
- the physical requirements – especially regarding stand-alone air-inlet devices – have been further clarified;
- [Clause 10](#) 'Labelling' has been updated;
- test for leakage in [A.3](#) has been updated;
- determination of flow rate in [A.5](#) has been totally reviewed;
- normative references in [Clause 2](#) and the Bibliography have 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.