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STN	**Infúzne prístroje na zdravotnícke použitie Časť 16: Infúzne súpravy na jednorazové použitie s regulátormi objemu infúzie (ISO 8536-16: 2025)**	**STN EN ISO 8536-16** 70 3350

Infusion equipment for medical use - Part 16: Infusion sets for single use with volumetric infusion controllers (ISO 8536-16:2025)

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. 10/25

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EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN ISO 8536-16

August 2025

ICS 11.040.20

English Version

Infusion equipment for medical use - Part 16: Infusion sets for single use with volumetric infusion controllers (ISO 8536-16:2025)

Matériel de perfusion à usage médical - Partie 16: Appareils de perfusion à usage unique avec régulateurs de perfusion volumétriques (ISO 8536-16:2025)

Infusionsgeräte zur medizinischen Verwendung - Teil 16: Infusionsgeräte mit volumetrischen Infusionsreglern zur einmaligen Verwendung (ISO 8536-16:2025)

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EN ISO 8536-16:2025 (E)

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European foreword

This document (EN ISO 8536-16:2025) 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of an identical text or by endorsement, at the latest by February 2026, and conflicting national standards shall be withdrawn at the latest by February 2026.

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International Standard

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Infusion equipment for medical use —

Part 16: Infusion sets for single use with volumetric infusion controllers

Matériel de perfusion à usage médical —

Partie 16: Appareils de perfusion à usage unique avec régulateurs de perfusion volumétriques

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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).

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

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International Standard **ISO 8536-16:2025(en)**

Infusion equipment for medical use —

Part 16:
Infusion sets for single use with volumetric infusion controllers

1 Scope

This document specifies the requirements for sterilized, single-use, gravity feed infusion sets, used together with the volumetric infusion controllers of IEC 60601-2-24.[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 3696, *Water for analytical laboratory use — Specification and test methods*

ISO 7000, *Graphical symbols for use on equipment — Registered symbols*

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

ISO 14644-1, *Cleanrooms and associated controlled environments — Part 1: Classification of air cleanliness by particle concentration*

ISO 15223-1, *Medical devices — Symbols to be used with information to be supplied by the manufacturer — Part 1: General requirements*