BS EN ISO 8536-16:2025

BSI Standards Publication

# Infusion equipment for medical use

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

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This British Standard is the UK implementation of EN ISO 8536-16:2025. It is identical to ISO 8536-16:2025.

The UK participation in its preparation was entrusted to Technical Committee CH/212, IVDs.

A list of organizations represented on this committee can be obtained on request to its committee manager.

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# 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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## 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of an identical text or by endorsement, at the latest by February 2026, and conflicting national standards shall be withdrawn at the latest by February 2026.

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The text of ISO 8536-16:2025 has been approved by CEN as EN ISO 8536-16:2025 without any modification.

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