

STN	Infúzne prístroje na zdravotnícke použitie Časť 15: Infúzne súpravy na jednorazové použitie s ochranou proti svetlu (ISO 8536-15: 2022/Amd 1: 2023) Zmena A1	STN EN ISO 8536-15/A1 70 3350
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Infusion equipment for medical use - Part 15: Light-protective infusion sets for single use (ISO 8536-15:2022)

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. 05/23

Obsahuje: EN ISO 8536-15:2022/A1:2023, ISO 8536-15:2022/Amd 1:2023

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EUROPEAN STANDARD

EN ISO 8536-15:2022/A1

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English Version

Infusion equipment for medical use - Part 15: Light-protective infusion sets for single use - Amendment 1 (ISO 8536-15:2022/Amd 1:2023)

Matériel de perfusion à usage médical -ζ Partie 15:
Perfuseurs photoprotecteurs à usage unique -ζ
Amendement 1 (ISO 8536-15:2022/Amd 1:2023)

Infusionsgeräte zur medizinischen Verwendung -
Teil15: Lichtbeständige Infusionsgeräte zur einmaligen
Verwendung - Änderung 1 (ISO 8536-15:2022/Amd
1:2023)

This amendment A1 modifies the European Standard EN ISO 8536-15:2022; it was approved by CEN on 30 January 2023.

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EUROPEAN COMMITTEE FOR STANDARDIZATION
COMITÉ EUROPÉEN DE NORMALISATION
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EN ISO 8536-15:2022/A1:2023 (E)

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European foreword

This document (EN ISO 8536-15:2022/A1:2023) 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of an identical text or by endorsement, at the latest by September 2023, and conflicting national standards shall be withdrawn at the latest by September 2023.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.

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According to the CEN-CENELEC Internal Regulations, the national standards organizations of the following countries are bound to implement this European Standard: Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Republic of North Macedonia, Romania, Serbia, Slovakia, Slovenia, Spain, Sweden, Switzerland, Türkiye and the United Kingdom.

Endorsement notice

The text of ISO 8536-15:2022/Amd 1:2023 has been approved by CEN as EN ISO 8536-15:2022/A1:2023 without any modification.

INTERNATIONAL STANDARD

ISO 8536-15

First edition
2022-03

AMENDMENT 1
2023-03

Infusion equipment for medical use — Part 15: Light-protective infusion sets for single use

AMENDMENT 1

Matériel de perfusion à usage médical —

Partie 15: Perfuseurs photoprotecteurs à usage unique

AMENDEMENT 1



Reference number
ISO 8536-15:2022/Amd.1:2023(E)

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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).

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