



SLOVENSKI STANDARD
SIST EN ISO 8536-15:2022/A1:2023

01-maj-2023

Infuzijska oprema za uporabo v medicini - 15. del: Infuzijski seti za enkratno uporabo, zaščiteni pred svetlobo - Dopnilo A1 (ISO 8536-15:2022/Amd 1:2023)

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

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

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

Ta slovenski standard je istoveten z: EN ISO 8536-15:2022/A1:2023

ICS:

11.040.20	Transfuzijska, infuzijska in injekcijska oprema	Transfusion, infusion and injection equipment
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SIST EN ISO 8536-15:2022/A1:2023 **en,fr,de**

EUROPEAN STANDARD

EN ISO 8536-15:2022/A1

NORME EUROPÉENNE

EUROPÄISCHE NORM

March 2023

ICS 11.040.20

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 -z Partie 15:
Perfuseurs photoprotecteurs à usage unique -z
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.

CEN members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for inclusion of this amendment into the relevant national standard without any alteration. Up-to-date lists and bibliographical references concerning such national standards may be obtained on application to the CEN-CENELEC Management Centre or to any CEN member.

This amendment exists in three official versions (English, French, German). A version in any other language made by translation under the responsibility of a CEN member into its own language and notified to the CEN-CENELEC Management Centre has the same status as the official versions.

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EUROPEAN COMMITTEE FOR STANDARDIZATION
COMITÉ EUROPÉEN DE NORMALISATION
EUROPÄISCHES KOMITEE FÜR NORMUNG

CEN-CENELEC Management Centre: Rue de la Science 23, B-1040 Brussels

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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.

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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

SIST EN ISO 8536-15:2022/A1:2023

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Foreword

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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*, 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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