SLOVENSKI STANDARD
SIST EN ISO 8536-15:2022

01-junij-2022

Infuzijska oprema za uporabo v medicini - 15. del: Infuzijski seti za enkratno uporabo, zaščiteni pred svetlobo (ISO 8536-15:2022)

Infusion equipment for medical use - Part 15: Light-protective infusion sets for single use (ISO 8536-15:2022)

Infusionsgeräte zur medizinischen Verwendung - Teil 15: Lichtbeständige Infusionsgeräte zur einmaligen Verwendung (ISO 8536-15:2022)

Matériel de perfusion à usage médical - Partie 15: Perfuseurs photoprotecteurs à usage unique (ISO 8536-15:2022)

Ta slovenski standard je istoveten z: **EN ISO 8536-15:2022**

ICS:

11.040.20	Transfuzijska, infuzijska in injekcijska oprema	Transfusion, infusion and injection equipment

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EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

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English Version

Infusion equipment for medical use - Part 15: Light-protective infusion sets for single use (ISO 8536-15:2022)

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European foreword

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of an identical text or by endorsement, at the latest by September 2022, and conflicting national standards shall be withdrawn at the latest by September 2022.

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Endorsement notice

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

INTERNATIONAL STANDARD

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Infusion equipment for medical use —

Part 15: Light-protective infusion sets for single use

Matériel de perfusion à usage médical —
Partie 15: Perfuseurs photoprotecteurs à usage unique

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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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Introduction

With the continuous development of infusion technology and the increasingly exacting clinical requirements, some infusion sets need to be adapted to specific clinical requirements.

Some pharmaceuticals, such as sodium nitroprusside, nitroglycerin and vitamin B2, are light sensitive and need to be clinically infused under light-protective conditions; this document is applicable to such sets.

This document stipulates the light-transmission requirements for the drip chamber and the tube. Since other components are limited by their external dimensions, they are not subject to light-transmission requirements and whether they will be light-protective or not is at the manufacturer's discretion.

It is the responsibility of the device manufacturer to keep the light-protection of the infusion sets stable during the shelf life. Annex A, Annex B and Annex C give the methods for evaluation of light-protective infusion sets.