ICS 11.040.20 SLOVENSKÁ TECHNICKÁ NORMA Jún 2022

STN	**Infúzne prístroje na zdravotnícke použitie Časť 15: Infúzne súpravy na jednorazové použitie s ochranou proti svetlu (ISO 8536-15: 2022)**	**STN EN ISO 8536-15** 70 3350

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. 05/22

Obsahuje: EN ISO 8536-15:2022, ISO 8536-15:2022

134890

Úrad pre normalizáciu, metrológiu a skúšobníctvo Slovenskej republiky, 2022
Slovenská technická norma a technická normalizačná informácia je chránená zákonom č. 60/2018 Z. z. o technickej normalizácii.

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN ISO 8536-15

March 2022

ICS 11.040.20

English Version

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

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

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

This European Standard was approved by CEN on 21 February 2022.

CEN members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for giving this European Standard the status of a 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 European Standard 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.

CEN members are the national standards bodies of 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, Turkey and United Kingdom.

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

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

© 2022 CEN All rights of exploitation in any form and by any means reserved worldwide for CEN national Members.

Ref. No. EN ISO 8536-15:2022 E

Contents

Page

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.

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.

Any feedback and questions on this document should be directed to the users’ national standards body/national committee. A complete listing of these bodies can be found on the CEN website.

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, Turkey and the United Kingdom.

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

ISO 8536-15

First edition
2022-03

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

Reference number
ISO 8536-15:2022(E)

© ISO 2022

COPYRIGHT PROTECTED DOCUMENT

© ISO 2022

All rights reserved. Unless otherwise specified, or required in the context of its implementation, no part of this publication may be reproduced or utilized otherwise in any form or by any means, electronic or mechanical, including photocopying, or posting on the internet or an intranet, without prior written permission. Permission can be requested from either ISO at the address below or ISO's member body in the country of the requester.

ISO copyright office
CP 401 • Ch. de Blandonnet 8
CH-1214 Vernier, Geneva
Phone: +41 22 749 01 11
Email: copyright@iso.org
Website: www.iso.org

Published in Switzerland

Contents

Page

© ISO 2022 – All rights reserved

Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

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).

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights. Details of any patent rights identified during the development of the document will be in the Introduction and/or on the ISO list of patent declarations received (see www.iso.org/patents).

Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

For an explanation of the voluntary nature of standards, the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT), see www.iso.org/iso/foreword.html.

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.

Any feedback or questions on this document should be directed to the user’s national standards body. A complete listing of these bodies can be found at www.iso.org/members.html.

© ISO 2022 – All rights reserved

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.

© ISO 2022 – All rights reserved

INTERNATIONAL STANDARD **ISO 8536-15:2022(E)**

Infusion equipment for medical use —

Part 15:
Light-protective infusion sets for single use

1 Scope

This document specifies the requirements for infusion sets for single use that use light-protective agents in the fluid path materials (henceforth abbreviated as "light-protective infusion sets").

This document also provides guidelines for performance and quality specifications of materials used in light-protective infusion sets.

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.

GB/T 601-2016, *Chemical reagent — Preparations of reference titration solutions*

ISO 8536 (all parts), *Infusion equipment for medical use*

koniec náhľadu – text ďalej pokračuje v platenej verzii STN

© ISO 2022 – All rights reserved