SLOVENSKI STANDARD
oSIST prEN ISO 8536-15:2021

01-april-2021

Infuzijska oprema za uporabo v medicini - 15. del: Infuzijski seti za enkratno uporabo, zaščiteni pred svetlobo (ISO/DIS 8536-15:2021)

Infusion equipment for medical use - Part 15: Light-protective infusion sets for single use (ISO/DIS 8536-15:2021)

Infusionsgeräte zur medizinischen Verwendung - Teil 15: Lichtbeständige Infusionsgeräte zur einmaligen Verwendung (ISO/DIS 8536-15:2021)

Matériel de perfusion à usage médical - Partie 15: Perfuseurs photoprotecteurs à usage unique (ISO/DIS 8536-15:2021)

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

ICS:

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

oSIST prEN ISO 8536-15:2021 **en,fr,de**

DRAFT INTERNATIONAL STANDARD

ISO/DIS 8536-15

ISO/TC **76**

Secretariat: **DIN**

Voting begins on:
2021-02-22

Voting terminates on:
2021-05-17

Infusion equipment for medical use —

Part 15:
Light-protective infusion sets for single use

ICS: 11.040.20

This document is circulated as received from the committee secretariat.

ISO/CEN PARALLEL PROCESSING

Reference number
ISO/DIS 8536-15:2021(E)

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Published in Switzerland

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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*.

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.

Introduction

With the continuous development of infusion technology and the increasingly exacting clinical requirements, some infusion sets adapted to specific clinical requirements have been produced in succession.

Some pharmaceuticals are light sensitive and need to be infused under light-protective conditions clinically, such as sodium nitroprusside, nitroglycerin and vitamin B2. Ordinary infusion sets conforming to other applicable parts of ISO 8536 cannot meet this infusion requirement, therefore, it is necessary to use the light-protective infusion set as specified in this part of ISO 8536.

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-protective infusion sets stable during the shelf life without decolourization. Annex B and Annex C of the standard give the methods for decolourization evaluation of light-protective infusion sets. The alternative solvents given in Annex C are more suitable for device manufacturers to perform decolourization tests.

Infusion equipment for medical use —

Part 15:
Light-protective infusion sets for single use

1 Scope

This part of ISO 8536 specifies the requirements for infusion sets that use light-protective agents in the fluid path materials (abbreviated as "light-protective infusion sets" henceforth).

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

2 Normative references

The following referenced documents are indispensable for the application of this document. For dated references, only 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 8536-4, *Infusion equipment for medical use — Part 4: Infusion sets for single use, gravity feed*

3 Terms and definitions

No terms and definitions are listed in this document.

ISO and IEC maintain terminological databases for use in standardization at the following addresses:

— ISO Online browsing platform: available at https://www.iso.org/obp

— IEC Electropedia: available at http://www.electropedia.org/

4 General requirements

Based on the infusion set used, the requirements of the corresponding part of ISO 8536 apply.

5 Materials

Light-protective infusion sets shall meet the physical requirements in Clause 6. Materials of light-protective infusion sets shall meet the chemical and biological requirements in Clause 7 and Clause 8.

6 Physical requirements

6.1 General

The physical requirements for the light-protective infusion set shall comply with the physical requirements of the applicable parts of ISO 8536 and the requirements given in 6.2 to 6.4.

6.2 Transparency

The fluid path of the light-protective infusion sets shall be transparent or sufficiently transparent, so that the interface between water and air can be distinguished with normal or corrected eyesight when bubbles pass through.

For infusion sets containing the drip chamber, the upper part of the drip chamber shall be sufficiently transparent to allow continuous observation of the droplets.

6.3 Light-protective performance

When tested in accordance with Annex A, the light transmittance of the light-protective infusion set in the wavelength range from 290 nm to at least 450 nm shall comply with Table 1.

NOTE 1 The specified wavelength range is in alignment with current provisions in USP 671. However, there might be pharmaceuticals requiring a broader spectrum.

Table 1 — Light transmittance limit of each component

Component	Light transmittance (%)
Drip chamber	≤ 35
Tube	≤ 15

NOTE 2 Components other than drip chambers and tubes when considered relevant for the intended application based on the related risks might require a different method of light transmission assessment that is not part of this document.

6.4 Decolourization

6.4.1 Outer surfaces of light-protective infusion sets shall not decolourize. Test in accordance with Annex B.

6.4.2 Inner surfaces of light-protective infusion sets shall not decolourize. Test in accordance with Annex C.

7 Chemical requirements

The requirements of ISO 8536-4 shall be met.

8 Biological requirements

The requirements of ISO 8536-4 shall be met.

9 Labelling

The requirements of the applicable part of ISO 8536 shall be met.

In addition, light-protective sets shall be labelled with the term “Light-protective set” or the relevant translation of this term.

The labelling of light-protective infusion sets shall include the wavelength spectrum for which the transmittance rates fulfil the requirements of Table 1.

The instructions for use (IFU) shall include a generic statement regarding the risks related to the effect of length of infusion and room conditions (e.g. surrounding light intensity), referring to the pharmaceutical manufacturers' monograph.

