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 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

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.

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.

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*

3 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

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

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

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

3.1
monograph
publication that specifies for a drug (or class of related drugs) the kinds and amounts of ingredients it can contain, the conditions and limitations for which it can be offered, directions for use, warnings, and other information required on its labelling

4 General requirements

Based on the infusion set used, the requirements of the corresponding part in the ISO 8536 series shall 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.