

First edition
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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

ISO 8536-15:2022/Amd 1:2023

<https://standards.iteh.ai/catalog/standards/sist/e238bff7-bdca-48c8-881e-090428429435/iso-8536-15-2022-amd-1-2023>



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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).

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Infusion equipment for medical use —

Part 15:

Light-protective infusion sets for single use

AMENDMENT 1

Normative references

Add the following references:

ISO 10993-17, *Biological evaluation of medical devices — Part 17: Establishment of allowable limits for leachable substances*

ISO 10993-18, *Biological evaluation of medical devices — Part 18: Chemical characterization of medical device materials within a risk management process*

6.4.3

Replace the text with the following:

Inner surfaces of light-protective infusion sets shall not decolourize. Test in accordance with Annex C or, alternatively, test in accordance with ISO 10993-18 and risk assess in accordance with ISO 10993-17. <http://www.itih.ai/catalog/standards/sist/e238b1f7-bdca-48c8-881e-090428429435/iso-8536-15-2022-amd-1-2023>

Bibliography

Replace entry [1] with the following:

[1] USP UNITED STATES PHARMACOPEIA, Chapter 671, <https://www.usp.org>