
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/PRF Amd 1

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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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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.iso.org/iso/standards/catalog/standards/sist/e238bfff7-bdca-48c8-881e-090428429435/iso-8536-15-2022-prf-amd-1>

Bibliography

Replace entry [1] with the following:

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