Second edition
2015-06-15

Infusion equipment for medical use —

Part 8:
Infusion sets for single use with pressure infusion apparatus

Matériel de perfusion à usage médical —

Partie 8: Appareils de perfusion non réutilisables avec des appareils de perfusion sous pression

Reference number
ISO 8536-8:2015(E)

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Foreword

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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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For an explanation on the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the WTO principles in the Technical Barriers to Trade (TBT) see the following URL: Foreword - Supplementary information

The committee responsible for this document is ISO/TC 76, *Transfusion, infusion and injection, and blood processing equipment for medical and pharmaceutical use*.

This second edition cancels and replaces the first edition (ISO 8536-8:2004), which has been technically revised with the following changes:

— The part title has been changed from 'Infusion equipment …' to 'Infusion sets …';

— The former Clause 4 on designation has been deleted;

— 6.14 has been amended and an appropriate Annex B 'Storage volume' added;

— Clause 10 on labelling was amended by a note regarding the usage of the symbol "XXX" according ISO 7000-2725;

— Clause 11 on disposal has been added;

— A.3 'Tests for leakage' has been amended;

— The former A.4 specifying a test of male conical fitting for leakage has been deleted;

— Normative references and the Bibliography have been updated;

— Document has been editorially revised.

ISO 8536 consists of the following parts, under the general title *Infusion equipment for medical use*:

— *Part 1*: *Infusion glass bottles*

— *Part 2: Closures for infusion bottles*

— *Part 3: Aluminium caps for infusion bottles*

— *Part 4: Infusion sets for single use, gravity feed*

— *Part 5: Burette infusion sets for single use, gravity feed*

— *Part 6: Freeze drying closures for infusion bottles*

— *Part 7: Caps made of aluminium-plastics combinations for infusion bottles*

— *Part 8: Infusion sets for single use with pressure infusion apparatus*

— *Part 9: Fluid lines for single use with pressure infusion equipment*

— *Part 10: Accessories for fluid lines for single use with pressure infusion equipment*

— *Part 11: Infusion filters for single use with pressure infusion equipment*

— *Part 12: Check valves*

The following parts are under preparation:

— *Part 13: Graduated flow regulators for single use with infusion sets*

— *Part 14: Clamps and flow regulators for transfusion and infusion equipment without fluid contact*