Sixth edition
2019-09

Infusion equipment for medical use —

Part 4:
Infusion sets for single use, gravity feed

Matériel de perfusion à usage médical —

Partie 4: Appareils de perfusion non réutilisables, à alimentation par gravité

Reference number
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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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This document was prepared by Technical Committee ISO/TC 76, *Transfusion, infusion and injection, and blood processing equipment for medical and pharmaceutical use*.

This sixth edition cancels and replaces the fifth edition (ISO 8536-4:2010), which has been technically revised. It also incorporates the Amendment ISO 8536-4:2010/Amd.1:2013.

The main changes compared to the previous edition are as follows:

— Clause 5 'Designation' now refers to Clause 10 'Labelling';

— the physical requirements – especially regarding stand-alone air-inlet devices – have been further clarified;

— Clause 10 'Labelling' has been updated;

— test for leakage in A.3 has been updated;

— determination of flow rate in A.5 has been totally reviewed;

— normative references in Clause 2 and the Bibliography have been updated.

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.

