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Infusion equipment for medical use —

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

Matériel de perfusion à usage médical —

Partie 5: Appareils non réutilisables de perfusion à burette, à alimentation par gravité

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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 document 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 third edition cancels and replaces the second edition (ISO 8536-5:2004), which has been technically revised.

The main changes are as follows:

— a change of scope to consider burettes as components of infusion sets;

— a scope expansion to include additional applications of burettes in transfusion applications;

— addition or revision of clauses concerning light-resistance, the graduated scale, particulate contamination, air-inlet, leakage, and drop former requirements;

— removal of clauses concerning labelling, packaging, and disposal;

— addition of Annexes A, B, and C.

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.

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Infusion equipment for medical use —

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

1 Scope

This document specifies requirements for single-use burettes to be used as subcomponents within sterilised infusion and transfusion sets for single use under gravity feed conditions or with pressure infusion apparatus.

NOTE 1 Annex B provides explanations about the history of the development of the standard and summarises the different arguments discussed within ISO/TC 76 during the collaboration of this document.

NOTE 2 Annex C provides recommendations regarding sustainability.

NOTE 3 Annex D provides information on attributive and variable testing.

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.

ISO 1135-4, *Transfusion equipment for medical use — Part 4: Transfusion sets for single use, gravity feed*

ISO 8536-4, *Infusion equipment for medical use — Part 4: Infusion sets for single use, gravity feed*

ISO 8536-8, *Infusion equipment for medical use — Part 8: Infusion sets for single use with pressure infusion apparatus*

ISO 8536-10, *Infusion equipment for medical use — Part 10: Accessories for fluid lines for single use with pressure infusion equipment*

ISO 8536-15, *Infusion equipment for medical use — Part 15: Light-protective infusion sets for single use*

ISO 10993-1, *Biological evaluation of medical devices — Part 1: Requirements and general principles for the evaluation of biological safety within a risk management process*

ISO 14971, *Medical devices — Application of risk management to medical devices*

ISO 24072, *Aerosol bacterial retention test method for air-inlet filter on administration devices*

IEC 62366-1, *Medical devices — Part 1: Application of usability engineering to medical devices*

3 Terms and definitions

No terms and definitions are listed in this document.

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/

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