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Infusion equipment for medical use —

Part 13: Graduated flow regulators for single use with fluid contact

Matériel de perfusion à usage médical —

Partie 13: Régulateurs de débit gradués non réutilisables avec contact à fluide

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Contents

Page

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).

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights. Details of any patent rights identified during the development of the document will be in the Introduction and/or on the ISO list of patent declarations received (see www.iso.org/patents).

Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

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 World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT) see the following URL: www.iso.org/iso/foreword.html.

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

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*

— *Part 13: Graduated flow regulators for single use with fluid contact*

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

Infusion equipment for medical use —

Part 13:
Graduated flow regulators for single use with fluid contact

1 Scope

This part of ISO 8536 specifies requirements for non-sterile, single-use graduated flow regulators used as subcomponents in sterilized infusion sets for single use to control the flow of intravenous infusion solutions with fluid contact under gravity feed conditions.

In some countries, the national pharmacopoeia or other national regulations are legally binding and take precedence over this part of ISO 8536.

2 Normative references

The following documents, in whole or in part, are normatively referenced in this document and are indispensable for its application. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

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

ISO 10993-1, *Biological evaluation of medical devices — Part 1: Evaluation and testing within a risk management process*

ISO 80000-4, *Quantities and units — Part 4: Mechanics*

3 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

3.1
graduated flow regulator
GFR
subcomponent with graduation and with fluid contact for setting certain flow of liquids

3.2
flow rate
volume per time

3.3
scale
array of marks, together with any associated figuring, in relation to which the position of the pointer is observed

4 Design

The GFR shall be designed for a constant flow regulation. The GFR shall be designed for a safe use to avoid accidental change of flow rate and shall clearly indicate open and off (closed) positions.

A typical design for a GFR is shown in Figure 1.