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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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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,* 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).

This second edition cancels and replaces the first edition (ISO 8536-13:2016), which has been technically revised.

The main changes are as follows:

— in Clause 3, the new term “activation” has been added;

— Figure 1 in Clause 4 has been amended to include markings on the open and close positions;

— former Clause 8 “Biological requirements” has been deleted due to the specified product being non-sterile;

— Annex A has been amended by a general introduction (see A.1) on the pre-conditioning of the sample;

— Annex A.5 has been amended to align the flow rate test method with other flow rate test methods in the ISO 8536 series;

— the Bibliography has 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.

Infusion equipment for medical use —

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

1 Scope

This document 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.

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 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.

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/

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

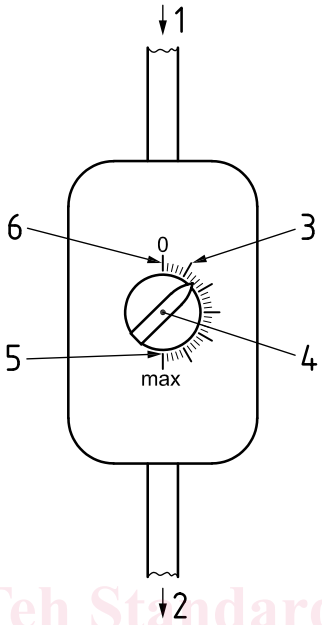
3.3
scale
array of marks, together with any associated figuring, in relation to which the position of the pointer is observed

3.4
activation
sequence of engaging the GFR from the open to the closed position then returning to the open position

4 Design

The GFR shall be designed for a constant flow regulation. When tested as specified in A.5.3, the stability of flow rate shall be at least within ±10 % during the test time. The GFR shall be designed for a safe use to avoid accidental change of flow rate and shall clearly indicate open and closed positions.

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



Key

1 upstream
2 downstream
3 scale
4 pointer
5 open position
6 closed position

Figure 1 — Example for the design of a GFR (schematic)

5 Materials

The materials used shall conform with the requirements specified in Clauses 6 and 7. In addition, the materials of all items described shall be assessed in accordance with the requirements of ISO 10993-1.

6 Physical requirements

6.1 Graduated scale

The scale shall indicate open and closed positions of the GFR plus scale positions as defined by the manufacturer.

6.2 Particulate contamination

The GFR shall be manufactured under conditions that minimize particulate contamination. The inner surface shall be smooth and clean. When tested as specified in A.2, after pre-conditioning in accordance with the general and specific conditions described in A.1, the number of particles shall not exceed the contamination index.