INTERNATIONAL STANDARD

ISO 8536-13

First edition
2016-10-01

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

Reference number
ISO 8536-13:2016(E)

ISO copyright office
Ch. de Blandonnet 8 • CP 401
CH-1214 Vernier, Geneva, Switzerland
Tel. +41 22 749 01 11
Fax +41 22 749 09 47
copyright@iso.org
www.iso.org

Contents

Page

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 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

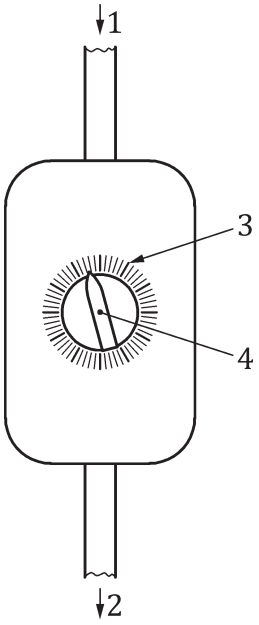
3.2
flow rate
volume per time

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.



Key

1 upstream
2 downstream
3 scale
4 pointer

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

5 Materials

The materials used shall comply with the requirements specified in Clauses 6, 7 and 8. In addition, the materials of all items described shall be assessed to the requirements of ISO 10993-1.

6 Physical requirements

6.1 Graduated scale

The scale shall give as minimum information open and closed position 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.1, the number of particles shall not exceed the contamination index.

6.3 Tensile strength

When tested as specified in A.2, the GFR shall withstand a static longitudinal tensile force of not less than 15 N for 15 s.

6.4 Leakage

6.4.1 The GFR shall be tight in the “Open” and “Off” positions and all other positions between “Open” and “Off”. When tested as specified in A.3.2 and A.3.4, there shall be no leakage.

6.4.2 In the “Off” position, the GFR shall close the line that there is no leakage between downstream and upstream. When tested as specified in A.3.3, there shall be no leakage.

6.5 Flow rates

The GFR shall deliver flow rates according to scale settings. When tested as specified in A.4, the GFR shall deliver this flow rate as specified by the manufacturer within given tolerances.

7 Chemical requirements

ISO 8536-4 applies.

8 Biological requirements

ISO 8536-4 applies.

Annex A
(normative)

Physical tests

A.1 Test for particulate contamination

Perform the test as specified in ISO 8536-4.

A.2 Test for tensile strength

Expose the GFR to be tested to a static longitudinal tensile force of 15 N for 15 s. Inspect whether points of connection and components withstand the test force applied.

A.3 Tests for leakage

A.3.1 In the beginning of the test, condition the GFR at the test temperature.

A.3.2 Set the GFR in "Open" position and connect it with one end closed to a compressed air supply. Immerse the GFR, with one end blocked in water at (40 ± 1) °C and apply air with an internal excess pressure of 50 kPa to the GFR. Inspect the GFR for any leakage of air in "Open" position for 15 s. Repeat the test at positions 25 %, 50 % and 75 % of scale.

A.3.3 Set the GFR in "Off" position and connect one end to a compressed air supply and leave the other end open. Immerse the open end of the GFR in water at (40 ± 1) °C and apply air with an internal excess pressure of 50 kPa to the GFR for 15 s. Inspect the open end of the GFR for any leakage of air. Finally, close the open end of the tube; keep the test sample under 50 kPa pressure and inspect for any leakage of air coming from the GFR.

A.3.4 Fill an infusion set with integrated GFR with setting "Open" position with degassed, distilled water; connect it with its openings sealed to a vacuum device and subject it to an internal excess pressure of −20 kPa at (40 ± 1) °C for 15 s. Atmospheric pressure shall be the reference pressure. Excess pressure, in accordance with ISO 80000-4, can assume positive or negative values. Ascertain whether air enters the infusion set. Repeat this test with GFR in position "Off" for another 15 s and continue to do it at 25 %, 50 % and 75 % of scale positions for the same time.

A.4 Determination of flow rate

A.4.1 Connect the GFR to an existing gravity infusion set or use a gravity infusion set with GFR integrated and condition at test temperature (23 ± 2) °C.

A.4.2 Prepare a container filled with sodium chloride solution [concentration (NaCl) = 9 g/l] at (23 ± 2) °C.

A.4.3 Pre-set the hydrostatic pressure at 1 m.

A.4.4 Prime the gravity infusion set while GFR is in "Open" position. Test the flow rate in three different positions of the scale: low, medium and high settings.

Measuring time shall be appropriate for the selected flow rates.

The flow rate accuracy shall be according to the specification of the manufacturer.

A.4.5 Prepare a container with sodium chloride solution [concentration (NaCl) = 9 g/l] and a gravity infusion set with GFR. Set the GFR at a medial position. Use a hydrostatic pressure of 1 m. Start the test and run for 15 min for stabilization followed by 6 consecutive hours and read the volume collected every hour. The stability of flow rate shall be at least within ±10 % during the test time.