DRAFT INTERNATIONAL STANDARD

ISO/DIS 8536-13

ISO/TC **76**

Secretariat: **DIN**

Voting begins on:
2015-06-25

Voting terminates on:
2015-09-25

Infusion equipment for medical use —

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

Matériel de perfusion à usage médical —

Partie 13: Crochets, inductances d'arrêts et régulateurs pour appareils de transfusion et infusion

ICS: 11.040.20

ISO/CEN PARALLEL PROCESSING

This draft has been developed within the International Organization for Standardization (ISO), and processed under the **ISO lead** mode of collaboration as defined in the Vienna Agreement.

This draft is hereby submitted to the ISO member bodies and to the CEN member bodies for a parallel five month enquiry.

Should this draft be accepted, a final draft, established on the basis of comments received, will be submitted to a parallel two-month approval vote in ISO and formal vote in CEN.

To expedite distribution, this document is circulated as received from the committee secretariat. ISO Central Secretariat work of editing and text composition will be undertaken at publication stage.

Reference number
ISO/DIS 8536-13:2015(E)

COPYRIGHT PROTECTED DOCUMENT

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 WTO principles in the Technical Barriers to Trade (TBT) see the following URL: Foreword - Supplementary information

ISO 8536-13 was prepared by Technical Committee 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*

The following parts are under development:

— *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 single use, gravity feed graduated flow regulators used to control the flow of intravenous infusion solutions with fluid contact.

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*

3 Terms and definitions

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

3.1
graduated flow regulator
GFR
device with fluid contact for regulating the flow of liquids

4 Design

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

5 Materials

The materials used shall comply with the requirements specified in Clause 6, Clause 7 and Clause 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 graduated flow regulator plus scale positions as defined by the manufacturer.

6.2 Particulate contamination

The graduated flow regulator 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 graduated flow regulator shall withstand a static longitudinal tensile force of not less than 15 N for 15 s.

6.4 Leakage

The graduated flow regulator shall be impermeable to microorganisms and fluids. When tested as specified in A.3 there shall be no leakage of air.

6.5 Flow rates

The graduated flow regulator shall deliver flow rates according to scale settings. When tested as specified in A.4 the graduated flow regulator 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.

9 Packaging

ISO 8536-4 applies.

10 Labelling

ISO 8536-4 applies. Labelling shall additionally contain reference to GFR.

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 Test 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 for 15 s. Inspect the GFR for any leakage of air.

A.3.3 Repeat test A.3.2 setting the GFR from “Open” to “Off” position, then return to open position again. Inspect the GFR for any leakage of air during the setting.

A.3.4 Set the GFR in “Off” position and connect it with one end open to a compressed air supply. Immerse 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 GFR for any leakage of air.

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 3 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 stabilisation followed by 6 consecutive hours and read every hour the volume collected. The stability of flow rate shall be at least within ± 10 % during the test time.

Annex ZA
(informative)

Relationship between this European Standard and the Essential Requirements of EU Directive 93/42/EEC on Medical Devices

This European Standard has been prepared under a mandate given to CEN by the European Commission and the European Free Trade Association to provide a means of conforming to Essential Requirements of Directive 93/42/EEC on Medical Devices.

Once this standard is cited in the Official Journal of the European Union under that Directive and has been implemented as a national standard in at least one Member State, compliance with the normative clauses of this standard confers, within the limits of the scope of this standard, a presumption of conformity with the relevant Essential Requirements of that Directive.

NOTE 1 Where a reference from a clause of this standard to the risk management process is made, the risk management process needs to be in compliance with Directive 93/42/EEC / Directive 90/385/EEC, as amended by 2007/47/EC. This means that risks have to be reduced “as far as possible”, “to a minimum”, “to the lowest possible level”, “minimized” or “removed”, according to the wording of the corresponding essential requirement.

NOTE 2 The manufacturer’s policy for determining **acceptable risk** must be in compliance with essential requirements 1, 2, 5, 6, 7, 8, 9, 11 and 12 of the directive.

NOTE 3 This Annex ZA is based on Normative References according to Table of References, replacing the references in the core text.

NOTE 4 When an Essential Requirement does not appear in Table ZA.1, it means that it is not addressed by this European Standard.

Table ZA.1 — Correspondence between this International Standard and Directive 93/42/EEC, Medical devices

Clause(s)/subclause(s) of this EN	Essential Requirements (ERs) of Directive 93/42/EEC	Qualifying remarks/Notes
4, 5, 6, 7, 8, 9, 10	7.2	Sections 7, 8, 9 and 10 refer to ISO 8536-4. The part of ER 7.2 relating to packaging is not addressed (for packaging see Clause 9 of this standard).
5, 6, 7, 8	7.3	Sections 7 and 8 refer to ISO 8536-4. ER covered by biological evaluation.
6.3, 6.4, A.2, A.3	7.5	Only the first sentence is covered. Presumption of conformity with the Essential Requirements relating to the biological evaluation can only be provided if the manufacturer chooses to apply the EN ISO 10993-series standards.
6.2, 6.3, 6.4, A.1, A.2, A.3	7.6	

Table ZA.1 *(continued)*

Clause(s)/subclause(s) of this EN	Essential Requirements (ERs) of Directive 93/42/EEC	Qualifying remarks/Notes
6.2, 6.3, 6.4, 7, 8, A.1, A.2, A.3	8.1	Sections 7 and 8 refer to ISO 8536-4. The part of ER 8.1 relating to handling is not addressed. Manufacturing processes are not covered. The reduction of the risk of infection is not fully covered.
9	8.3	Section 9 refers to ISO 8536-4. Only packaging related protection of sterility is covered.
8	8.4	Section 8 refers to ISO 8536-4. Only the sterilisation method is covered (section 8.2 in ISO 8536-4).
6.2, A.1	8.5	
9, 10	8.7	Sections 9, 10 refer to ISO 8536-4.
4	9.1	The second sentence of ER 9.1 is not addressed.
4, 5, 6	9.2	
6.3, A.2	12.7	Only 12.7.1 is addressed. Only tensile strength is addressed.
10	13.1	Section 10 refers to ISO 8536-4.
10	13.2	Refers to ISO 8536-4, 9.1 and 9.2. ISO 15223-1 is addressed when using symbols.
10	13.3	Section 10 refers to ISO 8536-4, 9.1 and 9.2. The part of 13.3a) relating to the authorized representative is not addressed. Presumption of conformity to the rest of 13.3a) is only provided if the name and address of the manufacturer are given. 13.3d) is only covered if the batch number is preceded by the word 'LOT'. 13.3f) Requirement „indication of single use must be consistent across the Community" is not addressed in ISO 8536-4. 13.3g, h) is not addressed in ISO 8536-4.
10	13.4	Section 10 refers to ISO 8536-4, 9.1 and 9.2. 13.4 is addressed regarding to the label.