SLOVENSKI STANDARD
oSIST prEN ISO 8536-14:2015

01-september-2015

Infuzijska oprema za uporabo v medicini - 14. del: Sponke in regulatorji pretoka transfuzijskih in infuzijskih naprav brez stika s tekočino (ISO/DIS 8536-14:2015)

Infusion equipment for medical use - Part 14: Clamps and flow regulators for transfusion and infusion equipment without fluid contact (ISO/DIS 8536-14:2015)

Infusionsgeräte zur medizinischen Verwendung - Teil 14: Klemmen und Durchflussregler für Transfusions- und Infusionsgeräte ohne Flüssigkeitskontakt (ISO/DIS 8536-14:2015)

Matériel de perfusion à usage médical - Partie 14 : Crochets et limiteur de débit pour appareils de transfusion et infusion sans contact à fluide (ISO/DIS 8536-14:2015)

Ta slovenski standard je istoveten z: **prEN ISO 8536-14**

ICS:

11.040.20	Transfuzijska, infuzijska in injekcijska oprema	Transfusion, infusion and injection equipment

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DRAFT INTERNATIONAL STANDARD

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Infusion equipment for medical use —

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

Matériel de perfusion à usage médical —

Partie 14: Crochets et limiteur de débit pour appareils detransfusion et infusion sans contact à fluide

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.

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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 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 8536-14 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 14:
Clamps and flow regulators for transfusion and infusion equipment without fluid contact

1 Scope

This part of ISO 8536 specifies requirements for devices used to control the flow of intravenous solutions and/or blood components through infusion and blood transfusion sets and blood bag assemblies without fluid contact. Such components may be an integral part of a medical device or a 'stand-alone' component.

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
clamp
subcomponent applied externally to an infusion/transfusion equipment with an 'on/off' function used to terminate or initiate the flow of fluid through the line

Note 1 to entry: The clamp may be an integral part of a medical device or a 'stand-alone' component and provide either permanent or temporary closure. The clamp does not breach the sterile fluid pathway.

3.2
flow regulator (with or without graduation)
subcomponent applied externally to an infusion/transfusion equipment to control the flow of fluid through the line within unspecified limits of accuracy

Note 1 to entry: The flow regulator may be an integral part of a medical device or a 'stand-alone' component. The subcomponent does not breach the sterile fluid pathway.

4 Design

Clamps and flow regulators shall be designed for their application in controlling fluid transfer in infusion/transfusion equipment. These devices shall be designed for safe use, avoiding accidental operation and shall not puncture or damage the flexible tubing during their operation.

Clamps and flow regulators are not supplied as sterile subcomponents but shall, when required, withstand sterilization.

Typical design for clamps and flow regulators is shown in Figures 1 to 3 below.

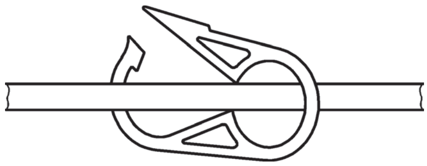

Figure 1 — Design of a pinch clamp

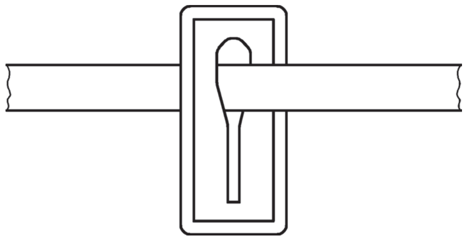

Figure 2 — Design of a slide clamp

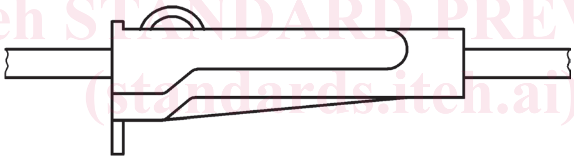

Figure 3 — Design of a flow regulator (known as roller clamp)

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 the ISO 10993- series.

6 Physical requirements

6.1 Tubing specifications

Clamps and flow regulators shall be capable of operating with flexible tubing within the range of external diameter, wall thickness and characteristics for which they are designed to be used.

NOTE Tubing attached to infusion/transfusion sets and blood bags is typically within the external diameter range 3,0 to 4,5 mm with a wall thickness from 0,4 to 0,6 mm. For neonatal and specific applications this may differ considerably.

6.2 Operating temperature

Clamps and flow regulators shall be capable of operating with flexible tubing in a temperature range suitable for the application of the medical device.

The temperature may vary from 4 °C to 40 °C.

6.3 Construction

Clamps and flow regulators shall accommodate the flexible tubing within a channel, slot or other suitable design in order to ensure that the entire external diameter of the tube is consistently restricted and fluid flow can be completely occluded during closure.

Clamps shall be designed either as 'temporary' or 'permanent' depending on their mode of action upon initial closure of the device. They shall be capable of locking with no more than one movement in a single plane. The clamps shall, when closed, resist the flow of fluid and air at an applied pressure of 50 kPa (see Annex A.1).

Permanent clamps shall be

— tamperproof;

— clearly distinguishable from temporary clamps (e.g. by colour coding).

Temporary clamps shall be

— re-openable (non-accidentally) by no more than two movements of its subcomponent parts;

— capable of being operated through defined cycles of opening and closure;

— clearly distinguishable from permanent clamps (e.g. by colour coding).

6.4 Flow rates

The flow regulator shall adjust the flow of the fluid between zero and the maximum. The flow regulator should be capable of continuous use throughout an application without the tubing being damaged. There should be no deleterious reaction between the flow regulator and the tubing when they are stored in such a way that there is contact.

For flow regulators without fluid contact with graduation testing shall be performed according A.2.

7 Chemical requirements

ISO 8536-4 applies.

8 Biological requirements

ISO 8536-4 applies.

9 Packaging

ISO 8536-4 applies.

Annex A
(normative)

Physical tests

A.1 Pressure test

A.1.1 In the beginning of the test, condition the whole system at the test temperature.

A.1.2 Set the clamp or flow regulator in the "Open" position and fit it to a line of the appropriate dimensions for the device with both ends open to a compressed air supply.

A.1.3 Fully close the clamp or flow regulator. Immerse the line and clamp or flow regulator in water at (40 ± 1) °C and apply air with an internal excess pressure of 50 kPa for 15 s to one end of the tube. Inspect the open end for any leakage of air.

A.1.4 If required by application, repeat test A.1.3 in water at the appropriate temperature and inspect the open end for any leakage of air.

A.2 Determination of flow rate for flow regulator with graduation

A.2.1 Apply the flow regulator to an existing gravity infusion set or use a gravity infusion set with flow regulator integrated and condition at test temperature (23 ± 2) °C.

A.2.2 Prepare a container filled with sodium chloride solution [concentration (NaCl) = 9 g/l] at (23 ± 2) °C.

A.2.3 Pre-set the hydrostatic pressure at 1 m.

A.2.4 Prime the gravity infusion set while flow regulator 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.2.5 Prepare a container with sodium chloride solution [concentration (NaCl) = 9 g/l] and a gravity infusion set with flow regulator. Set the flow regulator 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 every hour the volume collected. The stability of flow rate shall be at least within ± 10 % during the test time.