SLOVENSKI STANDARD
oSIST prEN ISO 8536-10:2013

01-december-2013

Infuzijska oprema za uporabo v medicini - 10. del: Dodatki za »fluidne« cevke za enkratno uporabo z infuzijsko opremo, delujočo na osnovi tlaka (ISO/DIS 8536-10:2013)

Infusion equipment for medical use - Part 10: Accessories for fluid lines for single use with pressure infusion equipment (ISO/DIS 8536-10:2013)

Infusionsgeräte zur medizinischen Verwendung - Teil 10: Zubehörteile für Übertragungsleitungen zur einmaligen Verwendung mit Druckinfusionsapparaten (ISO/DIS 8536-10:2013)

Matériel de perfusion à usage médical - Partie 10: Accessoires de tubulures pour utilisation avec des appareils de perfusion sous pression (ISO/DIS 8536-10:2013)

Ta slovenski standard je istoveten z: **prEN ISO 8536-10**

ICS:

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

oSIST prEN ISO 8536-10:2013 **en**

DRAFT INTERNATIONAL STANDARD

ISO/DIS 8536-10

ISO/TC **76**

Secretariat: **DIN**

Voting begins on:
2013-09-26

Voting terminates on:
2014-02-26

Infusion equipment for medical use —

Part 10:
Accessories for fluid lines for single use with pressure infusion equipment

Matériel de perfusion à usage médical —

Partie 10: Accessoires de tubulures non réutilisables avec des appareils de perfusion sous pression

[Revision of first edition (ISO 8536-10:2004)]

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 8536-10:2013(E)

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.

International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 2.

The main task of technical committees is to prepare International Standards. Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

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.

ISO 8536-10 was prepared by Technical Committee ISO/TC 76, *Transfusion, infusion and injection, and blood processing equipment for medical and pharmaceutical use*.

This second edition cancels and replaces the first edition (ISO 8536-10:2004), of which A.4 Tests for leakage has been amended and A.5 specifying a test for leakage of adapters with female and/or male conical fittings has been deleted. Clause 9 on labelling was amended by a note regarding the usage of the symbol "XXX" according ISO 7000-2725. Finally some minor editorial changes were introduced in the whole document.

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 equipment 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 preparation:

— *Part 13: Graduated flow regulators for single use with infusion sets*

Infusion equipment for medical use — Part 10: Accessories for fluid lines for single use with pressure infusion equipment

1 Scope

This part of ISO 8536 applies to sterilized accessories for single use in fluid lines and pressure infusion equipment as specified in ISO 8536-8.

This part of ISO 8536 includes:

a) Two-way stopcocks (2SC), three-way stopcocks (3SC), four-way stopcocks (4SC) and stopcocks manifold (SM);

NOTE Designation of a stopcock depends on the number of connections. The number of possible functional positions can be expressed by addition of a complementary note, using a diagonal stroke and a numeral indicating the number of possible stopcock positions, e. g. 3/4-way stopcock for three-way stopcock with four possible positions.

b) units with injection site (UIS) or check valve (UCV);

c) stoppers (S) or adapters (A).

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 594-2, *Conical fittings with 6 % (Luer) taper for syringes, needles and certain other medical equipment — Part 2: Lock fittings*

ISO 7000, *Graphical symbols for use on equipment — Index and synopsis*

ISO 7886-1, *Sterile hypodermic syringes for single use – Part 1: Syringes for manual use*

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

ISO 8536-8, *Infusion equipment for medical use — Part 8: Infusion set for single use with pressure infusion apparatus*

ISO 10993-4, *Biological evaluation of medical devices – Part 4: Selection of tests for interactions with blood*

ISO 15223-1, *Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied — Part 1: General requirements*

3 Designation

Designation of two-way stopcock (2SC) for infusions under pressure (P):

Two-way stopcock ISO 8536-10 — 2SC — P

Designation of three-way stopcock (3SC) for infusions under pressure (P):

Three-way stopcock ISO 8536-10 — 3SC — P

Designation of four-way stopcock (4SC) for infusions under pressure (P):

Four-way stopcock ISO 8536-10 — 4SC — P

Designation of stopcock manifold (SM) for infusions under pressure (P):

Stopcock manifold ISO 8536-10 — SM — P

Designation of two-stopcock manifold (2SM) for infusions under pressure (P):

Stopcock manifold ISO 8536-10 — 2SM — P

Designation of three-stopcock manifold (3SM) for infusions under pressure (P):

Stopcock manifold ISO 8536-10 — 3SM — P

Designation of four-stopcock manifold (4SM) for infusions under pressure (P):

Stopcock manifold ISO 8536-10 — 4SM — P

Designation of unit with injection site (UIS) for infusions under pressure (P):

Injection unit ISO 8536-10 — UIS — P

Designation of unit with check valve (UCV) for infusions under pressure (P):

Injection unit ISO 8536-10 — UCV — P

Designation of stopper (S) for infusions under pressure (P):

Stopper ISO 8536-10 — S — P

Designation of adapter (A) for infusions under pressure (P):

Adapter ISO 8536-10 — A — P

4 Materials

The materials from which the accessories as given in Clause 3 are manufactured shall comply with the requirements as specified in Clauses 5, 6 and 7.

5 Physical requirements

5.1 Avoidance of air bubbles

All components of accessories shall be designed such that no air bubbles are detected in flow channels when tested as specified in A.1.

5.2 Particulate contamination

The accessories shall be manufactured under conditions that minimize particulate contamination. The fluid pathway surfaces shall be smooth and clean. When tested as specified in A.2, the number of particles shall not exceed the contamination index.