SLOVENSKI STANDARD
oSIST prEN ISO 8536-8:2013

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Infuzijska oprema za uporabo v medicini - 8. del: Infuzijska oprema za enkratno uporabo s tlačno črpalko (ISO/DIS 8536-8:2013)

Infusion equipment for medical use - Part 8: Infusion equipment for single use with pressure infusion apparatus (ISO/DIS 8536-8:2013)

Infusionsgeräte zur medizinischen Verwendung - Teil 8: Infusionsgeräte zur einmaligen Verwendung mit Druckinfusionsapparaten (ISO/DIS 8536-8:2013)

Matériel de perfusion à usage médical - Partie 8: Matériel de perfusion non-réutilisables avec des appareils de perfusion sous pression (ISO/DIS 8536-8:2013)

Ta slovenski standard je istoveten z: **prEN ISO 8536-8**

ICS:

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

oSIST prEN ISO 8536-8:2013 **en**

DRAFT INTERNATIONAL STANDARD

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Infusion equipment for medical use —

Part 8:
Infusion equipment for single use with pressure infusion apparatus

Matériel de perfusion à usage médical —

Partie 8: Matériel de perfusion non-réutilisables avec avec des appareils de perfusion sous pression

[Revision of first edition (ISO 8536-8:2004)]

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 8536-8:2013(E)

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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.

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 8536-8 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 8536-8:2004, of which A.3 Tests for leakage has been amended and A.4 specifying a test of male conical fitting for leakage has been deleted. In addition 6.14 has been slightly amended. Clause 10 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 equiment for medical use — Part 8: Infusion equipment for single use with pressure infusion apparatus

1 Scope

This part of ISO 8536 gives users information on sterilized infusion sets for single use with pressure infusion equipment up to a maximum of 200 kPa (2 bar).

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*

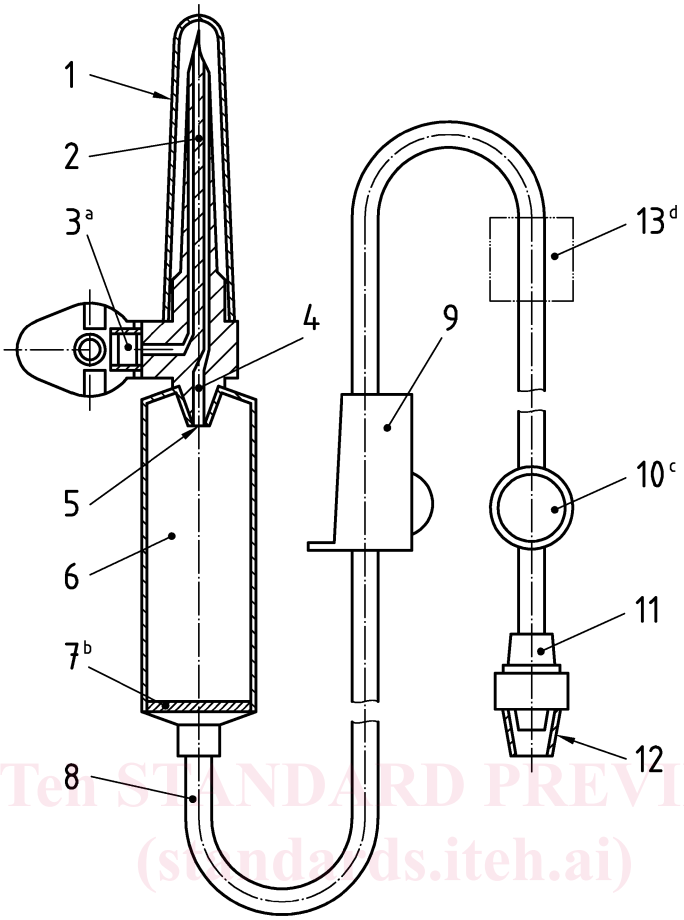
ISO 7000, *Graphical symbols for use on equipment — Index and synopsis*

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

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

3 General requirements

3.1 The nomenclature to be used for components of infusion sets and of a separate air-inlet device is given in Figures 1, 2 and 3. These figures illustrate examples of the configuration of infusion sets and air-inlet devices; other configurations may be used provided they lead to the same results. Infusion sets as illustrated in Figure 2 should only be used for collapsible plastics containers. Infusion sets as illustrated in Figure 2 used with separate air-inlet devices as illustrated in Figure 3, or infusion sets as illustrated in Figure 1 shall be used for rigid containers.



Key

1	protective cap of closure-piercing device	8	tubing
2	closure-piercing device	9	flow regulator
3	air-inlet with air filter and closure	10	injection site
4	fluid channel	11	male conical fitting
5	drip tube	12	protective cap of male conical fitting
6	drip chamber	13	flow element
7	fluid filter		

a Closure of air inlet is optional.

b The fluid filter may be positioned at other sites, preferably near the patient access. Generally, the fluid filter used has a nominal pore size of 15 µm.

c Injection site is optional.

d Optional element of infusion set which interfaces with pressure infusion equipment.

Figure 1 — Example of a vented infusion set