SLOVENSKI STANDARD
SIST EN ISO 8536-4:2005

01-marec-2005

Infuzijska oprema za uporabo v medicini ï 4. del: Infuzijski seti za enkratno uporabo, delujoļ i na osnovi gravitacije (ISO 8536-4:2004)

Infusion equipment for medical use - Part 4: Infusion sets for single use, gravity feed (ISO 8536-4:2004)

Infusionsgeräte zur medizinischen Verwendung - Teil 4: Infusionsgeräte für Schwerkraftinfusionen zur einmaligen Verwendung (ISO 8536-4:2004)

Matériel de perfusion a usage médical - Partie 4: Appareils de perfusion non réutilisables, a alimentation par gravité (ISO 8536-4:2004)

Ta slovenski standard je istoveten z: **EN ISO 8536-4:2004**

ICS:

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

SIST EN ISO 8536-4:2005 **en**

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN ISO 8536-4

August 2004

ICS 11.040.20

English version

Infusion equipment for medical use - Part 4: Infusion sets for single use, gravity feed (ISO 8536-4:2004)

Matériel de perfusion à usage médical - Partie 4: Appareils de perfusion non réutilisables, à alimentation par gravité (ISO 8536-4:2004)

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This European Standard was approved by CEN on 29 July 2004.

CEN members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for giving this European Standard the status of a national standard without any alteration. Up-to-date lists and bibliographical references concerning such national standards may be obtained on application to the Central Secretariat or to any CEN member.

This European Standard exists in three official versions (English, French, German). A version in any other language made by translation under the responsibility of a CEN member into its own language and notified to the Central Secretariat has the same status as the official versions.

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EUROPÄISCHES KOMITEE FÜR NORMUNG

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Ref. No. EN ISO 8536-4:2004: E

Foreword

This document (EN ISO 8536-4:2004) has been prepared by Technical Committee ISO/TC 76 "Transfusion, infusion and injection equipment for medical and pharmaceutical use" in collaboration with Technical Committee CEN/TC 205 “Non-active medical devices”, the secretariat of which is held by BSI.

This European Standard shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by February 2005, and conflicting national standards shall be withdrawn at the latest by February 2005.

According to the CEN/CENELEC Internal Regulations, the national standards organizations of the following countries are bound to implement this European Standard: Austria, Belgium, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Slovakia, Slovenia, Spain, Sweden, Switzerland and United Kingdom.

Endorsement notice

The text of ISO 8536-4:2004 has been approved by CEN as EN ISO 8536-4:2004 without any modifications.

INTERNATIONAL STANDARD

ISO 8536-4

Third edition
2004-08-15

Infusion equipment for medical use —

Part 4:
Infusion sets for single use, gravity feed

Matériel de perfusion à usage médical —

Partie 4: Appareils de perfusion non réutilisables, à alimentation par gravité

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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 8536-4 was prepared by Technical Committee ISO/TC 76, *Transfusion, infusion and injection equipment for medical and pharmaceutical use*.

This third edition cancels and replaces the second edition (ISO 8536-4:1998) which has been technically revised.

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 use with pressure infusion apparatus*

— *Part 9: Fluid lines for use with pressure infusion equipment*

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

— *Part 11: Infusion filters for use with pressure infusion equipment*

Infusion equipment for medical use —

Part 4:
Infusion sets for single use, gravity feed

1 Scope

This part of ISO 8536 specifies requirements for single-use, gravity feed infusion sets for medical use in order to ensure their compatibility with containers for infusion solutions and intravenous equipment.

Secondary aims of this part of ISO 8536 are to provide guidance on specifications relating to the quality and performance of materials used in infusion sets and to present designations for infusion set components.

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 referenced documents are indispensable for the application of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 594-1:1986, *Conical fittings with a 6 % (Luer) taper for syringes, needles and certain other medical equipment — Part 1: General requirements*

ISO 594-2:1998, *Conical fittings with 6 % (Luer) taper for syringes, needles and certain other medical equipment — Part 2: Lock fittings*

ISO 3696:1987, *Water for analytical laboratory use — Specification and test methods*

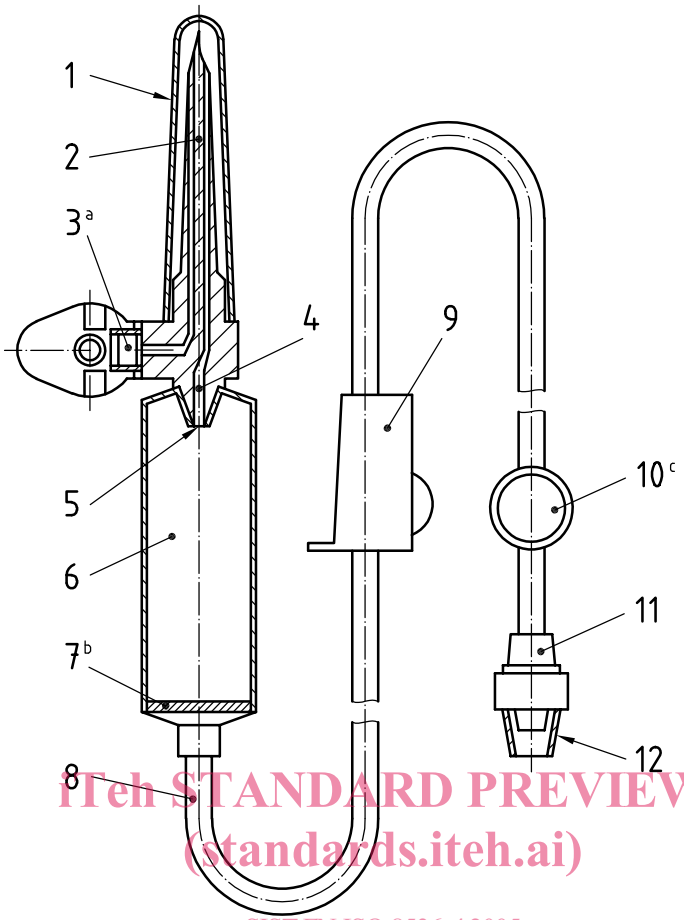
ISO 7864:1993, *Sterile hypodermic needles for single use*

ISO 14644-1:1999, *Cleanrooms and associated controlled environments — Part 1: Classification of air cleanliness*

ISO 15223, *Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied*

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

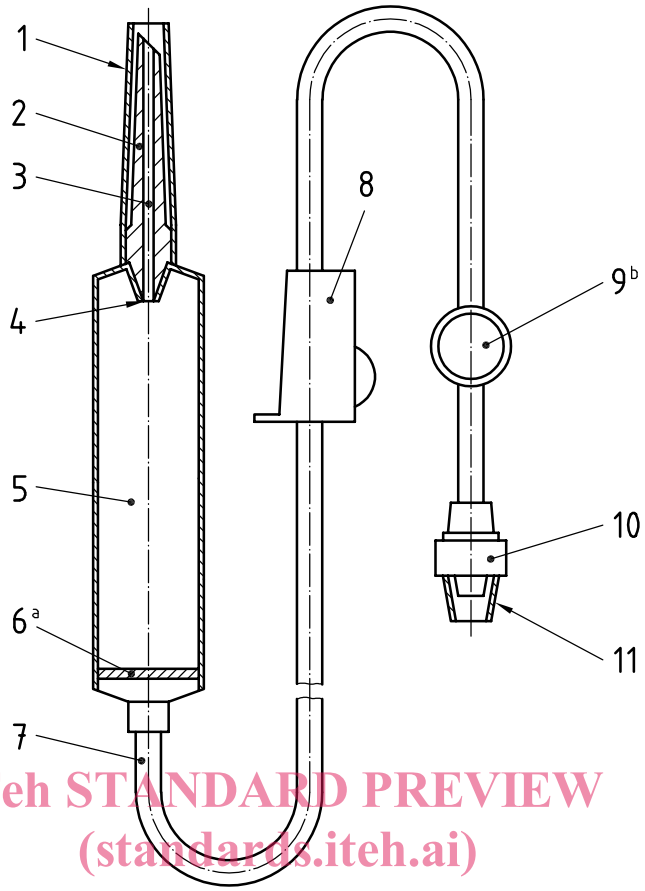
1	protective cap of closure-piercing device	7	fluid filter
2	closure-piercing device	8	tubing
3	air inlet with air filter and closure	9	flow regulator
4	fluid channel	10	injection site
5	drip tube	11	male conical fitting
6	drip chamber	12	protective cap of male conical fitting

[a] Closure of the 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] The injection site is optional.

Figure 1 — Example of a vented infusion set



Key

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

[a] 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.

[b] The injection site is optional.

Figure 2 — Example of a non-vented infusion set