Infusionsutrustning för medicinskt bruk –
Del 8: Infusionsaggregat för infusion med övertryck
för engångsbruk (ISO 8536-8:2004)

Infusion equipment for medical use –
Part 8: Infusion equipment for use with pressure
infusion apparatus (ISO 8536-8:2004)

EN ISO 8536-8

Infusion equipment for medical use - Part 8: Infusion equipment for use with pressure infusion apparatus (ISO 8536-8:2004)

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

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Foreword

This document (EN ISO 8536-8:2004) 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of an identical text or by endorsement, at the latest by February 2005, and conflicting national standards shall be withdrawn at the latest by February 2005.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 8536-8:2004 has been approved by CEN as EN ISO 8536-8:2004 without any modifications.
Infusion equipment for medical use —

Part 8:
Infusion equipment for 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 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 594-2:1998, Conical fittings with 6 % (Luer) taper for syringes, needles and certain other medical equipment — Part 2: Lock fittings

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

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

IEC 60601-2-24, Medical electrical equipment — Part 2-24: Particular requirements for the safety of infusion pumps and controllers

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

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 Injection site is optional.

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

Figure 2 — Example of a non-vented infusion set