PHILIPPINE NATIONAL STANDARD

PNS/BHDT ISO 8536-4:2007
(ISO published 2004)
ICS 11.040.20

Infusion equipment for medical use –
Part 4: Infusion sets for single use, gravity feed

BUREAU OF PRODUCT STANDARDS

Rec'd
25-5-07

National Foreword

This Philippine National Standard is identical with the International Standard ISO 8536-4:2004, Infusion equipment for medical use – Part 4: Infusion sets for single use, gravity feed. It was approved for adoption as a Philippine National Standard by the Bureau of Product Standards through the review and endorsement of the Technical Committee on Infusion Pumps of the Department of Health - Bureau of Health Devices and Technology (DOH-BHDT/TC 011).

Within the text of the standard, the following are the minimal editorial changes:

(a) the decimal comma shall be interpreted as a decimal point to be consistent with existing convention on Philippine number format.

(b) the words "International Standard" shall mean "National Standard."

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

Reference number
ISO 8536-4:2004(E)

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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*

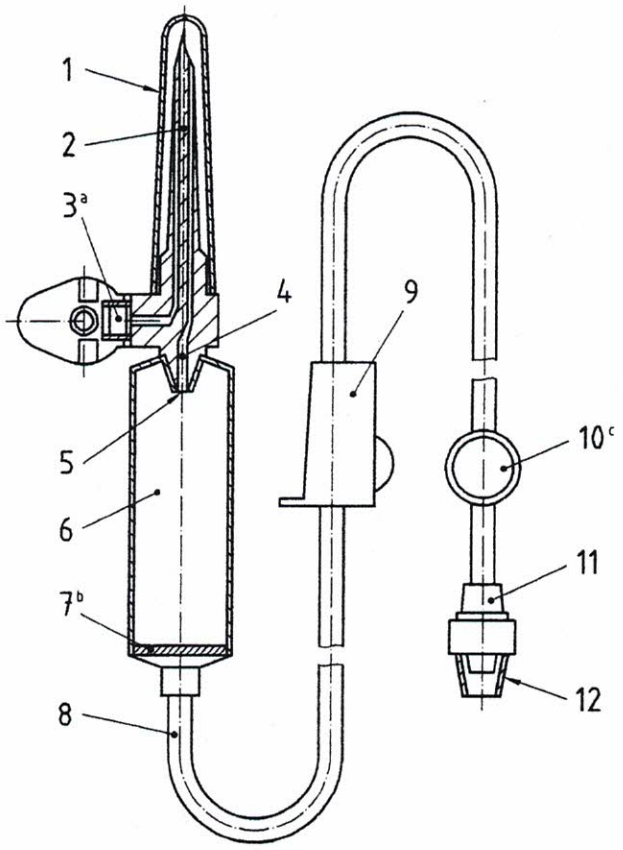
ISO 7864:1993, *Sterile hypodermic needles for single use*

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

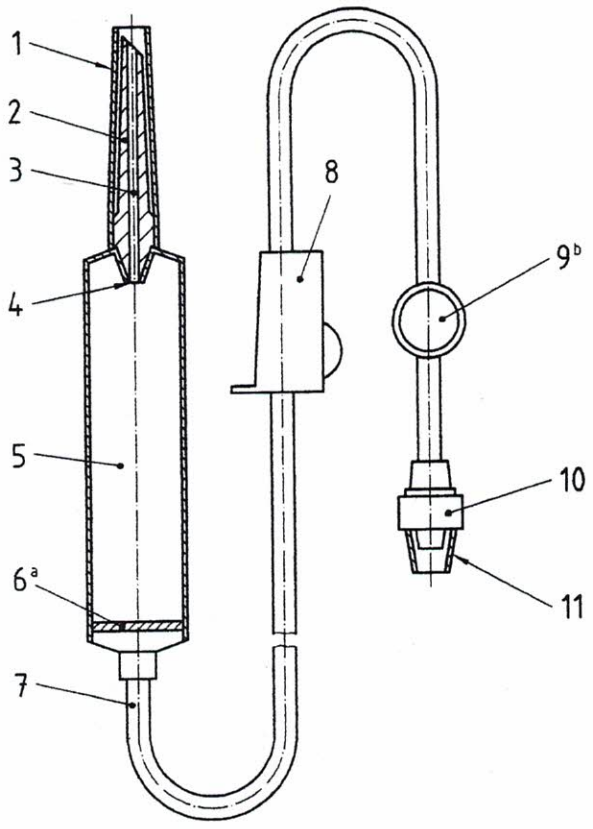
1	protective cap of closure-piercing device	7	fluid filter
2	closure-piercing device	8	tubing
3	air inlet with air filter and closure	9	flow regulator
4	fluid channel	10	injection site
5	drip tube	11	male conical fitting
6	drip chamber	12	protective cap of male conical fitting

[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
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

[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