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AMENDMENT 1
2013-03-01

Infusion equipment for medical use —

Part 4: Infusion sets for single use, gravity feed

AMENDMENT 1

Matériel de perfusion à usage médical —

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

AMENDEMENT 1

Reference number
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Foreword

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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.

Amendment 1 to ISO 8536-4:2010was prepared by Technical Committee ISO/TC 76, *Transfusion, infusion and injection, and blood processing equipment for medical and pharmaceutical use*.

Infusion equipment for medical use —

Part 4:
Infusion sets for single use, gravity feed

AMENDMENT 1

Page 8, 9.1

In alignment with ISO 1135-4:2012, 8.1:

— the note between e) and f) becomes NOTE 1;

— at the end of 9.1 add the following note:

NOTE 2 The presence of substances of interest can be indicated by using symbol 2725 of ISO 7000 by replacing the "XXX" with the abbreviation of the substance. The absence of substances of interest can be indicated by crossing the respective symbol.

Page 8, 9.2

In alignment with ISO 1135-4:2012, 8.2, add the following note at the end of 9.2:

NOTE The presence of substances of interest can be indicated by using symbol 2725 of ISO 7000 by replacing the "XXX" with the abbreviation of the substance. The absence of substances of interest can be indicated by crossing the respective symbol.

Page 9, Clause 11

In alignment with ISO 1135-4:2012, Clause 10, add the following new Clause 11:

11 Disposal

Information for secure and environmentally sound disposal of single-use infusion sets should be given, e.g. "Always dispose of blood contaminated products in a manner consistent with established biohazard procedures.

Page 11, A.2

Replace the entire clause with the following:

A.2 Tests for leakage

A.2.1 At the beginning of the test, the whole system shall be tempered at the test temperature.

A.2.2 Connect the infusion set with air supply and close all other openings. Apply air with an internal excess pressure of 50 kPa to the infusion set for 15 s. Inspect the infusion set for any leakage of air under water at 40 °C.

A.2.3 Fill the infusion set with degassed, distilled water, connect it with its openings sealed to a vacuum device and subject it to an internal excess pressure of −20 kPa at 40 °C for 15 s. Atmospheric pressure shall be the reference pressure. Excess pressure, in accordance with ISO 80000-4, can assume positive or negative values. Ascertain whether air enters the infusion set.

Page 13, Figure A.1

To clarify that the test apparatus in Figure A.1 is an example, change the figure title to the following:

Figure A.1 — Example apparatus setup for testing the efficiency of the fluid filter

Page 13, A.6

Amend the second sentence as follows:

Fill the infusion set with water in such a manner that no air bubbles are trapped and apply a pressure of 20 kPa above the atmospheric air pressure.

Page 17, Bibliography

In alignment with ISO 1135-4:2012 and the modifications to 9.1 and 9.2, add the following reference:

[2] ISO 7000, *Graphical symbols for use on equipment — Registered symbols*

Renumber subsequent references accordingly.