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AMENDMENT 1
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Infusion equipment for medical use —

Part 12: Check valves

AMENDMENT 1

Matériel de perfusion à usage médical —

Partie 12: Clapet antiretour

AMENDEMENT 1

Reference number
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Foreword

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Amendment 1 to ISO 8536-12:2007 was 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 12:
Check valves

AMENDMENT 1

Page 1, Clause 2

Replace the last entry, ISO 15223:2000, with the following:

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

Page 2, 6.4

In alignment with the deletion of A.4, delete the last sentence ("No water shall escape during the test specified in A.4.")

Page 3, 10.1

In alignment with the other parts of ISO 8536:

— in list items b), d), f) and k), replace the references to ISO 15223 with ISO 15223-1;

— in list item g), delete footnote 1;

— at the end of 10.1 add the following note:

> 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 4, 10.2

In alignment with the other parts of ISO 8536:

— in list items b) and g), replace the references to ISO 15223 with ISO 15223-1;

— in list item c), delete footnote 2;

— at the end of 10.2 add the following note:

> 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 5, A.3

Replace the entire clause with the following:

A.3 Test for leakage of the valve housing

A.3.1 At the beginning of the test the whole system shall be tempered at the test temperature.

A.3.2 Immerse the check valve, with downstream end blocked, in water at 40 °C and apply an internal air pressure of 50 kPa for 15 s. Examine the check valve for air leakage.

A.3.3 Subject the check valve, at both ends, to distilled water at an internal excess pressure of 200 kPa at 40 °C for 15 min. Check for water leaks.

A.3.4 Fill the built-in check valve with degassed distilled water at 40 °C, connect the downstream opening, with the upstream opening sealed, to a vacuum device and subject it to an internal excess pressure of –20 kPa for 15 s. Inspect whether air enters the housing section of the check valve.

Page 5, A.4

Delete the entire clause. Renumber subsequent clauses accordingly.

Page 5, A.5

Amend existing A.5 as follows:

Subject the check valve to a water excess pressure of 200 kPa in the counterflow direction at 40 °C for 15 min in each case. Check for leakage through the check valve.

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