INTERNATIONAL STANDARD

ISO 8536-12

Second edition
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Infusion equipment for medical use —

Part 12: Check valves for single use

Matériel de perfusion à usage médical —

Partie 12: Clapets antiretour à usage unique

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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.

The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular, the different approval criteria needed for the different types of ISO documents should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see www.iso.org/directives).

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. Details of any patent rights identified during the development of the document will be in the Introduction and/or on the ISO list of patent declarations received (see www.iso.org/patents).

Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

For an explanation of the voluntary nature of standards, the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT), see www.iso.org/iso/foreword.html.

This document was prepared by Technical Committee ISO/TC 76, *Transfusion, infusion and injection, and blood processing equipment for medical and pharmaceutical use*, in collaboration with the European Committee for Standardization (CEN) Technical Committee CEN/TC 205, *Non-active medical devices*, in accordance with the Agreement on technical cooperation between ISO and CEN (Vienna Agreement).

This second edition cancels and replaces the first edition (ISO 8536-12:2007), which has been technically revised. It also incorporates the Amendment ISO 8536-12:2007/Amd.1:2012.

The main changes compared to the previous edition are as follows:

— the title of this document has been amended by "for single use";

— Clause 3 has been completely reviewed;

— Clause 4, 'Designation' refers now to 'Labelling';

— the requirement on tensile strength has been deleted;

— the connecting requirements have been aligned to the ISO 80369 series;

— Clause 11 has been added;

— Annex A has been completely updated and aligned with the physical requirements given in Clause 6;

— the normative references have been updated;

— a bibliography has been added;

— complete editorial review.

A list of all parts in the ISO 8536 series can be found on the ISO website.

Any feedback or questions on this document should be directed to the user's national standards body. A complete listing of these bodies can be found at www.iso.org/members.html.

Infusion equipment for medical use —

Part 12:
Check valves for single use

1 Scope

This document specifies requirements for check valves intended for single use and used with infusion equipment both with gravity-feed infusion and with pressure infusion apparatus.

The functional requirements in this document also apply to inline check valves.

2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements 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 7886-1, *Sterile hypodermic syringes for single use — Part 1: Syringes for manual use*

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

ISO 8871-1, *Elastomeric parts for parenterals and for devices for pharmaceutical use — Part 1: Extractables in aqueous autoclavates*

ISO 8871-2, *Elastomeric parts for parenterals and for devices for pharmaceutical use — Part 2: Identification and characterization*

ISO 10993-1, *Biological evaluation of medical devices — Part 1: Evaluation and testing within a risk management process*

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

ISO 80369 (all parts), *Small-bore connectors for liquids and gases in healthcare applications*

3 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

ISO and IEC maintain terminological databases for use in standardization at the following addresses:

— ISO Online browsing platform: available at https://www.iso.org/obp

— IEC Electropedia: available at http://www.electropedia.org/

3.1
blocking
prevention of counterflow through the *check valve* (3.2)

3.2
check valve
valve that allows flow only in one direction

Note 1 to entry: A check valve is normally in the closed position.

3.3
inline check valve
check valve (3.2) that is a built-in feature of the infusion set

3.4
flow rate
rate of flow through an open *check valve* (3.2) in the flow direction

3.5
backflow leak rate
rate of counterflow through a closed *check valve* (3.2)

3.6
opening pressure
pressure to open the *check valve* (3.2) in flow direction

3.7
anti-siphon valve
check valve (3.2) that requires an *opening pressure* (3.6) higher than 2 kPa to open the check valve in flow direction

4 Designation

Designation shall follow label requirements in accordance with Clause 9.

5 Materials

The materials used shall be chosen so that the check valves conform with the requirements specified in Clauses 6, 7 and 8.

If rubber is used as a material, the requirements given in ISO 8871-1 and ISO 8871-2 shall apply.

6 Physical requirements

6.1 Particulate contamination

The check valve shall be manufactured under conditions that minimize particulate contamination. All parts shall be smooth and clean at the fluid pathway surfaces. When tested as specified in ISO 8536-4 the number of particles shall not exceed the contamination index limit.

6.2 Leakage

The check valve, when tested in accordance with Clause A.2, shall show no signs of air leakage.

6.3 ISO 80369 (all parts) compatibility

Any inlet and/or outlet without a tube bond port shall have a connector as specified in the ISO 80369 series.

6.4 Counterflow pressure resistance

The check valve shall withstand a pressure of 200 kPa in the counterflow direction when tested in accordance with Clause A.3.