INTERNATIONAL STANDARD

ISO 8536-12

Second edition
2021-02

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

Reference number
ISO 8536-12:2021(E)

ISO copyright office
CP 401 • Ch. de Blandonnet 8
CH-1214 Vernier, Geneva
Phone: +41 22 749 01 11
Email: copyright@iso.org
Website: www.iso.org

Published in Switzerland

Contents

Page

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.

6.5 Flow rate

When the check valve is connected to the infusion equipment, the flow rate shall not be less than 6 l/h when tested in accordance with Clause A.4.

6.6 Blocking performance

The check valve shall close at a pressure of not more than 2 kPa in its counterflow direction when tested in accordance with Clause A.5.

6.7 Opening pressure

The check valve shall open at a pressure of not more than 2 kPa when tested in accordance with A.6.1 and A.6.2.

NOTE An opening pressure of 2 kPa does not apply to "high-pressure valves" such as anti-siphon valves and imaging valves.

6.8 Protective caps

The protective caps shall cover the respective surfaces of the check valve to prevent contamination from surrounding environment, to avoid stick injuries and packaging damages. Protective caps should be secure but easily removable.

7 Chemical requirements

The chemical requirements shall be in accordance with ISO 8536-4.

8 Biological requirements

8.1 General

The check valve shall be assessed for biological compatibility in accordance with ISO 10993-1.

8.2 Sterility

Sterility shall be in accordance with ISO 8536-4.

8.3 Pyrogenicity

Pyrogenicity shall be in accordance with ISO 8536-4.

9 Labelling

9.1 General

The labelling shall include the requirements as specified in 9.2 and 9.3. If graphical symbols are used, then refer to ISO 15223-1.

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

9.2 Label on unit container

The unit container shall be labelled at least with the following information:

a) the name and address of the manufacturer;

b) a description of the contents;

c) indication that the check valve is free from pyrogens, or that the check valve is free from bacterial endotoxins;

d) indication that the check valve is sterile, using the graphical symbol as given in ISO 15223-1;

e) the lot (batch) designation, prefixed by the word LOT, or using the graphical symbol as given in ISO 15223-1;

f) year and month of expiry, accompanied by appropriate wording or the graphical symbol as given in ISO 15223-1;

g) indication that the check valve is for single use only, or equivalent wording, or using the graphical symbol as given in ISO 15223-1;

h) instructions for use, including warnings, e.g. about detached protective caps (instructions for use may also take the form of an insert);

i) the letter "P", which stands for pressure, or the letter "G", which stands for gravity, and whose type height shall stand out clearly from surrounding text.

If the available space is too small to give all this information in legible characters and/or symbols, the information may be reduced to e) and f). In this case the information as required in this sub-clause shall be given on the label of the next bigger shelf or multi-unit container.

9.3 Label on shelf or multi-unit container

The shelf or multi-unit container shall be labelled at least with the following information:

a) the name and address of the manufacturer;

b) a description of the contents;

c) the lot (batch) designation, prefixed by the word LOT, or using the graphical symbol as given in ISO 15223-1;

d) year and month of expiry, accompanied by appropriate wording or the graphical symbol as given in ISO 15223-1;

e) the letter "P", which stands for pressure, or the letter "G", which stands for gravity and whose type height shall stand out clearly from surrounding text;

f) a storage note, if any.

10 Packaging

Packaging shall be in accordance with ISO 8536-4.

11 Disposal

Information for secure and environmentally sound disposal of single-use check valves should be given.

EXAMPLE Disposal of blood contaminated products must always be done in a manner consistent with established biohazard procedures.

Annex A
(normative)

Physical tests

A.1 General

All physical tests shall be performed at a temperature of (23 ± 2) °C unless other temperatures are given in the test method.

A.2 Test 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 inlet of the check valve with air supply and close all remaining openings. Apply air with an internal positive pressure of 50 kPa to the check valve for 15 s. Atmospheric pressure shall be the reference pressure. Inspect the check valve for any leakage of air under water at (40 ± 1) °C.

A.2.3 Fill the whole system with degassed and distilled water. Connect the check valve to a vacuum device and close all remaining openings. Apply vacuum with an internal negative pressure of 20 kPa to the check valve for 15 s. Atmospheric pressure shall be the reference pressure. Inspect if air enters into the check valve or test system.

A.2.4 If used with pressure sets, this additional test shall be performed. Connect the inlet of the check valve with air supply and close all the remaining openings. Apply air pressure with an internal positive pressure of 200 kPa to the check valve for 15 s. Atmospheric pressure shall be the reference pressure. Inspect the check valve for any leakage of air under water at (40 ± 1) °C.

A.3 Test for pressure resistance in counterflow direction

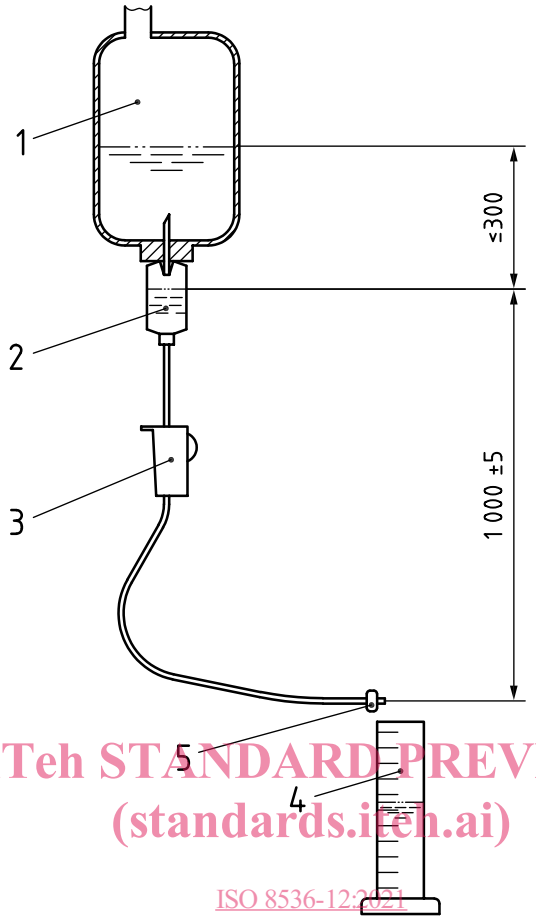
Subject the check valve to a water pressure of 200 kPa in the counterflow direction at (40 ± 1) °C for 15 min. Check for leakage through the check valve.

A.4 Determination of flow rate

A.4.1 Use a container or bag filled with a minimum 1 000 ml of distilled or sterile water. If a rigid or semi-rigid container is used, the container shall be cut open at the top to provide a freely vented system. Insert the closure-piercing device of the infusion set into the container or bag port. Fill the drip chamber to be about ⅔ full. Open the flow regulator and fill the set with water. Close the flow regulator. Arrange the test setup so that there is a height of (1 000 ± 5) mm between the liquid level in the drip chamber and the outlet of the set at the beginning of the test. The liquid level between that in the drip chamber and the container or bag shall not exceed 300 mm (see Figure A.1).

A.4.2 Attach the check valve under test at the end of the set. Open the clamp or the flow regulator and set it to maximum flow. Measure the amount of distilled (or sterile) water flowing through the check valve in 1 min.

Dimensions in millimetres



Key

1 bag or container
2 closure-piercing device or drip chamber
3 clamp or flow regulator
4 measuring cylinder
5 test specimen (check valve)

Figure A.1 — Example test setup to determine flow rate

A.5 Test for blocking performance

A.5.1 The check valve shall be connected to the testing system as shown in the flow diagram in Figure A.2. Connect the test specimen (check valve) to the setup using adequate connectors and/or components. The check valve shall be tested in the downstream position.

A.5.2 The entire system shall be filled with the distilled or sterile water, taking care to avoid air bubbles. The following test steps shall then be performed.

A.5.3 Adjust the test setup according to “Position 1”.

A.5.3.1 Prime all lines until the system is free of any air.