



SLOVENSKI STANDARD
oSIST prEN ISO 8536-12:2020
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Infuzijska oprema za uporabo v medicini - 12. del: Kontrolni ventili za enkratno uporabo (ISO/DIS 8536-12:2020)

Infusion equipment for medical use - Part 12: Check valves for single use (ISO/DIS 8536-12:2020)

Infusionsgeräte zur medizinischen Verwendung - Teil 12: Rückschlagventile zur einmaligen Verwendung (ISO/DIS 8536-12:2020)

Matériel de perfusion à usage médical - Partie 12: Clapet antiretour non réutilisables (ISO/DIS 8536-12:2020)

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ICS:

11.040.20	Transfuzijska, infuzijska in injekcijska oprema	Transfusion, infusion and injection equipment
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Infusion equipment for medical use —

Part 12: Check valves for single use

*Matériel de perfusion à usage médical —**Partie 12: Clapet antiretour non réutilisables*

ICS: 11.040.20

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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 on 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*.

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

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

- the title of this document standard has been amended by "for single use";
- the Clause 'Terms and definitions' has been completely reviewed;
- the Clause 'Designation' refers now to Clause 'Labelling';
- the requirement on tensile strength has been deleted;
- the connecting requirements have been aligned to the ISO 80369 series;
- a new Clause 'Disposal' has been added;
- the [Annex A](#) 'Physical tests' has been completely updated and aligned with the physical requirements given in [Clause 6](#);
- the 'Normative references' and the 'Bibliography' have been updated;
- 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.

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

ISO 8536-8, *Infusion equipment for medical use — Part 8: Infusion sets for single use with pressure infusion apparatus*

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 (series), *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 <http://www.iso.org/obp>

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

3.1

blocking

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

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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) which requires an *opening pressure* (3.6) higher than 2 kPa to open the *check valve* (3.2) in flow direction

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4 Designation

Designation shall follow label requirements according to [Clause 9.020](#)

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5 Materials

The materials used shall be chosen so that the check valves comply with the requirements specified in [Clauses 6, 7](#) and [8](#).

If rubber is used as a material, the requirements laid down 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 [A.2](#), shall show no signs of air leakage.

6.3 ISO 80369 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 [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 [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 [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

See ISO 8536-4.

8 Biological requirements

8.1 General

The check valve shall be assessed for biological compatibility according to ISO 10993-1.

8.2 Sterility

See ISO 8536-4.

8.3 Pyrogenicity

See ISO 8536-4.