SLOVENSKI STANDARD
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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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Infusion equipment for medical use —

Part 12: Check valves for single use

Matériel de perfusion à usage médical —

Partie 12: Clapet antiretour non réutilisables

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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 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)

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

4 Designation

Designation shall follow label requirements according to Clause 9.

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.

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 2725 of ISO 7000 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 according to ISO 15223-1;

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

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

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

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

f) a storage note, if any.

