BS EN ISO 8536-9:2015

BSI Standards Publication

Infusion equipment for medical use

Part 9: Fluid lines for single use with pressure infusion equipment

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National foreword

This British Standard is the UK implementation of EN ISO 8536-9:2015. It supersedes BS EN ISO 8536-9:2004 which is withdrawn.

The UK participation in its preparation was entrusted to Technical Committee CH/212, IVDs.

A list of organizations represented on this committee can be obtained on request to its secretary.

This publication does not purport to include all the necessary provisions of a contract. Users are responsible for its correct application.

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Compliance with a British Standard cannot confer immunity from legal obligations.

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English Version

Infusion equipment for medical use - Part 9: Fluid lines for single use with pressure infusion equipment (ISO 8536-9:2015)

Matériel de perfusion à usage médical - Partie 9: Tubulures non réutilisables avec des appareils de perfusion sous pression (ISO 8536-9:2015)

Infusionsgeräte zur medizinischen Verwendung - Teil 9: Übertragungsleitungen zur einmaligen Verwendung mit Druckinfusionsapparaten (ISO 8536-9:2015)

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This European Standard exists in three official versions (English, French, German). A version in any other language made by translation under the responsibility of a CEN member into its own language and notified to the CEN-CENELEC Management Centre has the same status as the official versions.

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COMITÉ EUROPÉEN DE NORMALISATION
EUROPÄISCHES KOMITEE FÜR NORMUNG

CEN-CENELEC Management Centre: Avenue Marnix 17, B-1000 Brussels

Ref. No. EN ISO 8536-9:2015 E

European foreword

This document (EN ISO 8536-9:2015) has been prepared by Technical Committee ISO/TC 76 “Transfusion, infusion and injection, and blood processing equipment for medical and pharmaceutical use” in collaboration with Technical Committee CEN/TC 205 “Non-active medical devices” the secretariat of which is held by DIN.

This European Standard shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by December 2015, and conflicting national standards shall be withdrawn at the latest by December 2015.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. CEN [and/or CENELEC] shall not be held responsible for identifying any or all such patent rights.

This document supersedes EN ISO 8536-9:2004.

In this edition, the following changes have been made:

— the former Clause 3 on designation has been deleted;

— 5.8 has been amended and an appropriate Annex C added;

— Clause 9 on labelling was amended by addition of information regarding the usage of the symbol “XXX” according ISO 7000, Symbol 2725;

— Clause 10 on disposal has been added;

— A.4 has been amended;

— the former A.5 specifying a test for leakage of adapters with female and/or male conical fittings has been deleted;

— normative references and the Bibliography have been updated;

— document has been editorially revised..

This document has been prepared under a mandate given to CEN by the European Commission and the European Free Trade Association, and supports essential requirements of EU Directive(s).

For relationship with EU Directive, see informative Annex ZA, which is an integral part of this document.

According to the CEN-CENELEC Internal Regulations, the national standards organizations of the following countries are bound to implement this European Standard: Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, Former Yugoslav Republic of Macedonia, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and the United Kingdom.

Endorsement notice

The text of ISO 8536-9:2015 has been approved by CEN as EN ISO 8536-9:2015 without any modification.

Table — Correlations between undated normative references and dated EN and ISO standards

Normative references as listed in Clause 2	Equivalent dated standard	
	EN	ISO
ISO 594-2	–-	ISO 594-2:1998
ISO 7000	–-	ISO 7000:2014
ISO 7864	EN ISO 7864:1995	ISO 7864:1993
ISO 8536-10	EN ISO 8536-10:2015	ISO 8536-10:2015
ISO 8536-11	EN ISO 8536-11:2015	ISO 8536-11:2015
ISO 10993-4	EN ISO 10993-4:2009	ISO 10993-4:2002 plus Amd.1:2006
ISO 15223-1	EN ISO 15223-1:2012	ISO 15223-1:2012

Annex ZA
(informative)

Relationship between this European Standard and the Essential Requirements of EC Directive 93/42/EEC on medical devices

This European Standard has been prepared under a mandate given to CEN by the European Commission and the European Free Trade Association to provide a means of conforming to Essential Requirements of the New Approach Directive 93/42/EEC on medical devices

Once this standard is cited in the Official Journal of the European Communities under that Directive and has been implemented as a national standard in at least one Member State, compliance with the clauses of this standard given in Table ZA.1 confers, within the limits of the scope of this standard, a presumption of conformity with the corresponding Essential Requirements of that Directive and associated EFTA regulations

Table ZA.1 — Correspondence between this European Standard and Directive 93/42/EEC on medical devices

Clause(s)/subclause(s) of this EN	Essential Requirements (ERs) of Directive 93/42/EEC	Qualifying remarks/Notes
Clause 3, 4.1, 4.2, 4.3, 4.4, 4.5, 4.8, 4.9, Clause 6	7.2	The part of ER 7.2 relating to packaging is not addressed. For packaging see Clause 7 of this standard.
4.1, 4.2, 4.3, 4.4, 4.5, 4.8, 4.9, Clause 6	7.3	ER covered by biological evaluation.
4.3, 4.4, A.3, A.4	7.5	Only the first sentence is covered. Presumption of conformity with the Essential Requirements relating to the biological evaluation can only be provided if the manufacturer chooses to apply the ISO 10993-series of standards.
4.2, 4.3	7.6	
4.2, 4.3, 4.4	8.1	The part of ER 8.1 relating to handling is not addressed. Manufacturing processes are not covered. Only sterility of product is covered.
	8.3	
6.1	8.4	Only the sterilization method is covered.
4.2	8.5	
8.2, 8.3	8.7	
4.5, 4.8, 8.2 g)	9.1	The second sentence of ER 9.1 is not addressed.

Clause(s)/subclause(s) of this EN	Essential Requirements (ERs) of Directive 93/42/EEC	Qualifying remarks/Notes
Clause 3, 4.1, 4.2, 4.3, 4.4, 4.5, 4.8, 4.9	9.2	
4.8	10.1 to 10.3	
4.3, A.3	12.7.1	Only tensile strength is addressed.
8	13.1	
8.2 d), e), f), g), 8.3 c)	13.2	
8.2, 8.3	13.3	The part of 13.3 a) relating to the authorized representative is not addressed. Presumption of conformity to the rest of 13.3 a) is only provided if the name and address of the manufacturer are given. 13.3 d) is only covered if the batch number is preceded by the word 'LOT'. 13.3 f) Requirement „indication of single use must be consistent across the Community“ is not addressed in the standard. 13.3 g), h) is not addressed in the standard.
8.2, 8.3	13.4	13.4 is addressed regarding to the label.
8.2, 8.3	13.5	13.5 is not addressed regarding to the detachable components.
8.2, 8.3	13.6	13.6 e), f), h), i), j), l), m), o) are not applicable for devices according to this standard 13.6 q) is not addressed.

WARNING — Other requirements and other EC Directives may be applicable to the product(s) falling within the scope of this standard

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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 meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the WTO principles in the Technical Barriers to Trade (TBT) see the following URL: Foreword - Supplementary information.

The committee responsible for this document is 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 8536-9:2004), which has been technically revised with the following changes:

— The former Clause 3 on designation has been deleted;

— 5.8 has been amended and an appropriate Annex C has been added;

— Clause 9 on labelling was amended by addition of information regarding the usage of the symbol "XXX" according ISO 7000, symbol 2725;

— Clause 10 on disposal has been added;

— A.4 has been amended;

— The former A.5 specifying a test for leakage of adapters with female and/or male conical fittings has been deleted;

— Normative references and the Bibliography have been updated;

— document has been editorially revised.

ISO 8536 consists of the following parts under the general title *Infusion equipment for medical use*:

— *Part 1*: *Infusion glass bottles*

— *Part 2: Closures for infusion bottles*

— *Part 3: Aluminium caps for infusion bottles*

— *Part 4: Infusion sets for single use, gravity feed*

— *Part 5: Burette infusion sets for single use, gravity feed*

— *Part 6: Freeze drying closures for infusion bottles*

— *Part 7: Caps made of aluminium-plastics combinations for infusion bottles*

— *Part 8: Infusion sets for single use with pressure infusion apparatus*

— *Part 9: Fluid lines for single use with pressure infusion equipment*

— *Part 10: Accessories for fluid lines for single use with pressure infusion equipment*

— *Part 11: Infusion filters for single use with pressure infusion equipment*

— *Part 12: Check valves*

The following parts are under preparation:

— *Part 13: Graduated flow regulators for single use with infusion sets*

— *Part 14: Clamps and flow regulators for transfusion and infusion equipment without fluid contact*

Infusion equipment for medical use —

Part 9:
Fluid lines for single use with pressure infusion equipment

1 Scope

This part of ISO 8536 applies to sterilized fluid lines for single use for use with pressure infusion equipment up to a maximum of 200 kPa (2 bar).

The following items are covered by this part of ISO 8536:

a) syringe pump lines (SPL);

b) connecting lines (CL);

c) lines with integrated injection cannula (LIC).

In some countries, the national pharmacopoeia or other national regulations are legally binding and take precedence over this part of ISO 8536.

2 Normative references

The following documents, in whole or in part, are normatively referenced in this document and are indispensable for its application. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 594-2,[1)] *Conical fittings with 6 % (Luer) taper for syringes, needles and certain other medical equipment — Part 2: Lock fittings*

ISO 7000, *Graphical symbols for use on equipment — Registered symbols*

ISO 7864, *Sterile hypodermic needles for single use*

ISO 8536-4:2010, *Infusion equipment for medical use — Part 4: Infusion sets for single use, gravity feed*

ISO 8536-10, *Infusion equipment for medical use — Part 10: Accessories for fluid lines for single use with pressure infusion equipment*

ISO 8536-11, *Infusion equipment for medical use — Part 11: Infusion filters for single use with pressure infusion equipment*

ISO 10993-4, *Biological evaluation of medical devices — Part 4: Selection of tests for interactions with blood*

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

3 Termes and definitions

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

NOTE These terms and definitions are specifically applicable to Annex C.

1) To be replaced by ISO 80369-7.

3.1
filling volume
V_F
volume of tube during „pressure less“-filling respectively filling by gravity, the tube remains unstressed

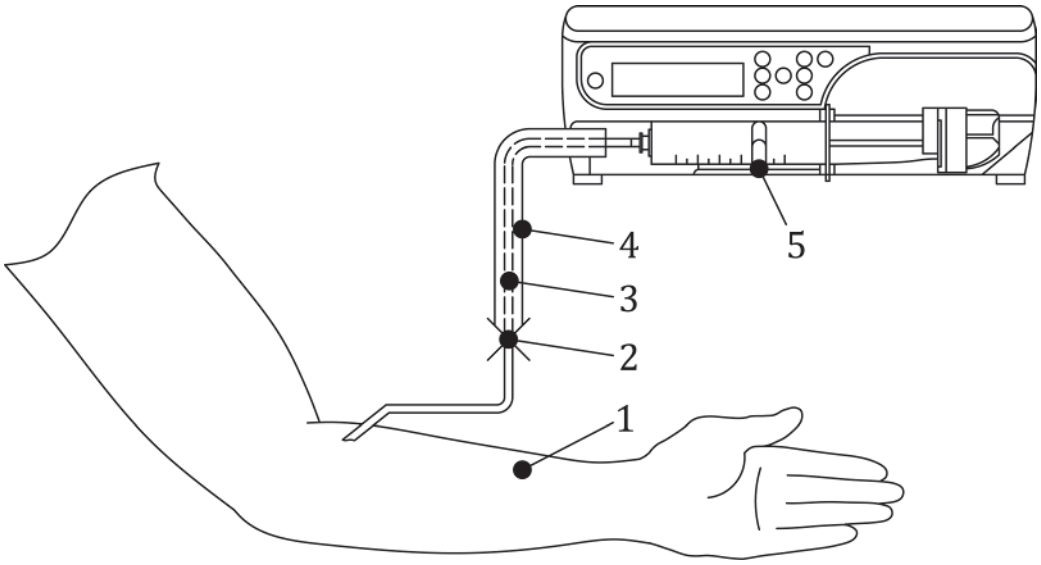
Note 1 to entry: The filling volume is to be equated with the calculated volume of the tube.

3.2
storage volume
V_S
tube volume during pressurization equal to filling volume (V_F) plus bolus volume (V_S):

$$V_S = V_F + V_B$$

3.3
bolus volume
V_B
increased tube volume during pressurization (storage volume V_S) in comparison to the unstressed tube (filling volume V_F)

Note 1 to entry: For illustration of the bolus volume see Figure 1.



Key
1 patient
2 occlusion
3 tube
4 bolus volume
5 syringe pump

Figure 1 — Bolus volume

4 Materials

The materials from which the fluid lines are manufactured shall comply with the requirements as specified in Clause 5, Clause 6, and Clause 7.

5 Physical requirements

5.1 Transparency

Tubing of fluid lines shall be transparent. When tested as specified in A.1, the air-water interface shall be detectable.

5.2 Particulate contamination

The fluid lines shall be manufactured under conditions that minimize particulate contamination. The fluid pathway surfaces shall be smooth and clean. When tested as specified in A.2, the number of particles shall not exceed the contamination index.

5.3 Tensile strength

When tested as specified in A.3, all parts of a fluid line shall withstand a static tensile force of at least 15 N for 15 s.

5.4 Leakage

In the beginning of the test, the whole system shall be conditioned at the test temperature.

The fluid lines shall be impermeable to air, microorganisms, and fluids. When tested as specified in A.4, there shall be no leakage of air or water.

5.5 Adapters with female and/or male conical fittings

In the beginning of the test, the whole system shall be conditioned at the test temperature.

Adapters shall be provided with a connector with female conical fitting and/or a connector with male conical fitting according to ISO 594-2.

5.6 Accessories

Accessories of fluid lines, other than infusion filters, shall comply with the requirements as specified in ISO 8536-10.

5.7 Filters

Infusion filters shall comply with the requirements as specified in ISO 8536-11.

5.8 Storage volume

The storage volume shall be stated according to 9.2 i). For a definition of the storage volume and for a test method for the determination of the storage volume, see Annex C.

5.9 Injection needles

Injection needles shall comply with ISO 7864 when tested as specified in A.5.

5.10 Protective caps

ISO 8536-4 applies.

6 Chemical requirements

ISO 8536-4 applies. For test methods, see Annex B.

7 Biological requirements

7.1 Sterility

The fluid lines in their unit container shall have been subjected to a validated sterilization process (see Reference [2] to Reference [5]).

7.2 Pyrogens

The fluid lines shall be assessed for freedom from pyrogens using a suitable test and the results shall indicate that the fluid lines are free from pyrogens. Guidance on testing for pyrogenicity is given in ISO 8536-4.

7.3 Haemolysis

The fluid lines shall be assessed for freedom from haemolytic constituents and the result shall indicate that the fluid lines are free from haemolytic reactions.

Guidance on testing for haemolytic constituents is given in ISO 10993-4.

8 Packaging

ISO 8536-4 applies.

9 Labelling

9.1 General

The labelling shall include the requirements as specified in 9.2 and 9.3. If graphical symbols are used, 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) name and address of the manufacturer;

b) textual description of the contents, e.g. cannular line for single use;

c) indication that the fluid line is free from pyrogens or that the fluid line is free from bacterial endotoxins;

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

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

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

g) indication that the fluid line 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) storage volume shall be labelled according C.3;

j) the letter "P" which stands for pressure and the type height of which 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 subclause 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) name and address of the manufacturer;

b) textual description of the contents, e.g. cannular line for single use;

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

d) the letter "P" which stands for pressure and the type height of which shall stand out clearly from surrounding text;

e) storage note.

10 Disposal

Information for a secure and environmentally sound disposal of single-use infusion sets should be given.

EXAMPLE "Always dispose of blood contaminated products in a manner consistent with established biohazard procedures."

Annex A
(normative)

Physical tests

A.1 Test for transparency

Fill the fluid line with distilled water. Visually inspect whether the air-water interface is detectable.

A.2 Test for particulate contamination

The volume of rinse fluid shall be at least 50 times the inner volume of a test specimen. The test shall be performed as specified in ISO 8536-4.

A.3 Test for tensile strength

Expose the fluid lines in longitudinal direction to a static tensile force of 15 N for 15 s. Inspect whether points of connection and components withstand the test force applied.

A.4 Tests for leakage

A.4.1 In the beginning of the test, the whole system shall be tempered at the test temperature.

A.4.2 Connect the fluid lines with the air supply using a male and/or female connector in accordance with ISO 594-2 and close all other openings. Apply air with an internal excess pressure of 50 kPa to the fluid lines for 15 s. Inspect the fluid lines for any leakage of air under water at (40 ± 1) °C.

A.4.3 Fill the fluid lines with distilled water and apply an internal excess pressure of 200 kPa for 15 min. Inspect the fluid lines for any leakage of water at (40 ± 1) °C.

A.5 Injection needle test

The test shall be done in accordance with ISO 7864.

Annex B
(normative)

Chemical tests

B.1 Preparation of test fluids

Take 450 cm of tubing and the equivalent of 100 cm^2 of surface of all the other components, e.g. connecting pieces. Disassemble the sterilised, ready-to-use fluid line into those pieces which will be in contact with the infusion fluid then arrange these pieces according to identical materials.

Reduce the pieces in size so that all inner and outer surfaces can be wetted. Then fill them into a 250 ml wide-neck Erlenmeyer flask, add 200 ml of distilled water as specified in the current edition of the pharmacopoeia, cover the flask, and keep for 24 h at (37 ± 1) °C.

Fill another Erlenmeyer flask with 200 ml of distilled water as specified in the current edition of the pharmacopoeia, cover the flask, and keep for 24 h at (37 ± 1) °C. This is used as control fluid for testing according to ISO 8536-4:2010, B.2.

B.2 Test procedures

The tests shall be performed as specified in ISO 8536-4 but using the test fluids as specified in B.1 of this part of ISO 8536.

Annex C
(normative)

Storage volume

C.1 General

This Annex clarifies the different measurable tube volumes by providing a clear definition and a test method for the determination of each of the volumes.

C.2 Determination of tube volumes

C.2.1 Filling volume (V_F)

The filling volume of the tube is solely calculated. The calculation is effected with the nominal inner diameter of the tube according to Formula (C.1):

$$V_F = \frac{d^2 \cdot \pi}{4} \cdot l \qquad \text{(C.1)}$$

where

d is the nominal inner diameter of the tube;

l is the length of the tube.

C.2.2 Bolus volume (V_B)

C.2.2.1 General

The bolus volume is difficult to be determined only by calculation considering all variables (e.g. inner diameter, wall thickness, hardness of tube, temperature influence). Therefore, determination of the bolus volume is made according to the following test conditions (see also Figure C.1):

— room temperature (23 ± 2) °C;

— test medium distilled water, temperature of test medium (40 ± 1) °C;

— internal excess pressure of 200 kPa. Duration of pressurization 15 s;

— all test samples are in a ready for use condition, e.g. sterile;

— length of tube 2 000 mm plus connectors;

— for “rigid” connectors, the volume difference under pressurization is zero.

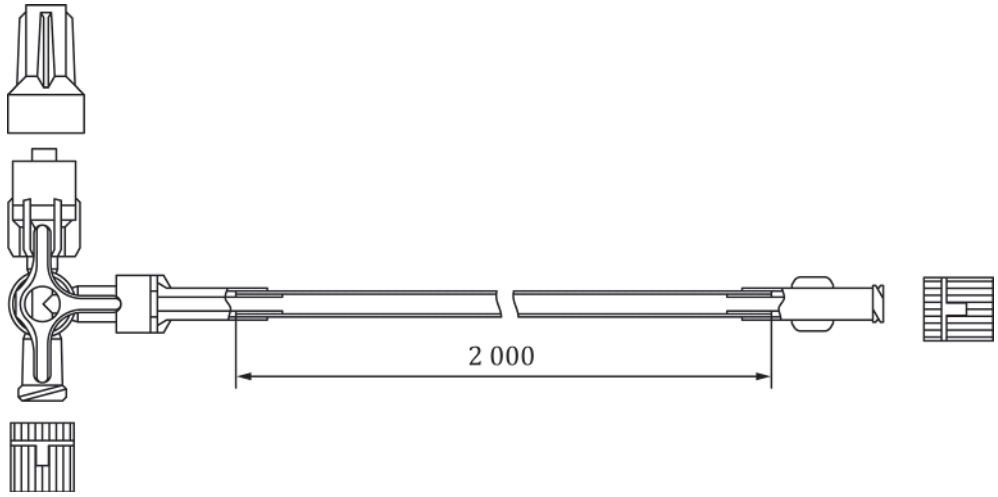


Figure C.1 — Test apparatus for determination of the bolus volume

C.2.2.2 Procedure

For the determination of the bolus volume, the following procedural steps have to be performed.

a) Filling of test sample without air bubbles with test medium.

b) Occlusion of tube outlet with closure plug and the tube inlet by turning the three-way stopcock.

c) Determine weight of the test sample filled without pressure = M_1.

d) Open the three-way stopcock, apply the test pressure (fluid pressure) to the three-way stopcock, wait until test pressure has stabilized and maintain it for 15 s, then close the three-way stopcock.

e) Determine weight of the test sample filled with pressure = M_2.

f) Calculation of bolus volume (V_B) by means of weight difference (1 g = 1 ml), as given in Formula (C.2):

$$V_B = \frac{M_2 - M_1}{l} \tag{C.2}$$

where

M_1 is the weight without pressure;

M_2 is the weight with pressure;

l is the length of the tube.

C.2.3 Storage volume (V_S)

The storage volume of the tube is calculated by addition of the filling volume (V_F) and the bolus volume (V_B), as shown in Formula (C.3):

$$V_S = V_F + V_B \tag{C.3}$$

C.3 Labelling

Due to the term definition of filling volume, storage volume, and bolus volume not being known to every user, these terms have been replaced by the general information “VOL” (volume). This is supplemented by an indication of temperature and pressure conditions. The information given always refers to a tube

length of 1 m to facilitate a simple conversion and/or calculation for the user in case of a partial occlusion. An example for labelling is given in Figure C.2:

— accuracy of volume specification: 1 ml;

— design of specification.

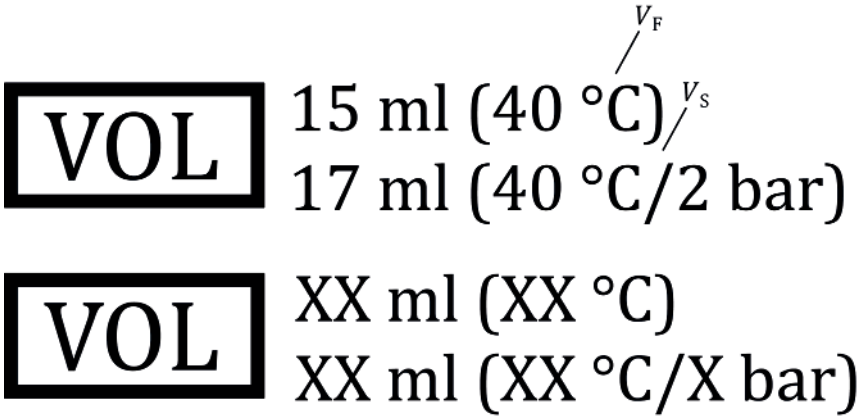


Figure C.2 — Example for labelling

Bibliography

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

[2] ISO 11135, *Sterilization of health care products — Ethylene oxide — Requirements for development, validation and routine control of a sterilization process for medical devices*

[3] ISO 11137-1, *Sterilization of health care products — Radiation — Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices*

[4] ISO 11137-2, *Sterilization of health care products — Radiation — Part 2: Establishing the sterilization dose*

[5] ISO 17665-1, *Sterilization of health care products — Moist heat — Part 1: Requirements for the development, validation and routine control of a sterilization process for medical devices*

[6] EN 15986, *Symbol for use in the labelling of medical devices — Requirements of medical devices containing phthalates*

[7] European Pharmacopoeia

[8] United States Pharmacopoeia

[9] Japanese Pharmacopoeia

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