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Intravascular catheters — Sterile and single-use catheters —

Part 1:
General requirements

Cathéters intravasculaires — Cathéters stériles et non réutilisables —

Partie 1: Exigences générales

[Revision of first edition (ISO 10555-1:1995) and ISO 10555-1:1995/Amd.1:1999 and ISO 10555-1:1995/Amd.2:2004]

ICS 11.040.25

ISO/CEN PARALLEL PROCESSING

This draft has been developed within the International Organization for Standardization (ISO), and processed under the **ISO-lead** mode of collaboration as defined in the Vienna Agreement.

This draft is hereby submitted to the ISO member bodies and to the CEN member bodies for a parallel five-month enquiry.

Should this draft be accepted, a final draft, established on the basis of comments received, will be submitted to a parallel two-month approval vote in ISO and formal vote in CEN.

In accordance with the provisions of Council Resolution 15/1993 this document is circulated in the English language only.

Conformément aux dispositions de la Résolution du Conseil 15/1993, ce document est distribué en version anglaise seulement.

To expedite distribution, this document is circulated as received from the committee secretariat. ISO Central Secretariat work of editing and text composition will be undertaken at publication stage.

Pour accélérer la distribution, le présent document est distribué tel qu'il est parvenu du secrétariat du comité. Le travail de rédaction et de composition de texte sera effectué au Secrétariat central de l'ISO au stade de publication.

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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.

International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 2.

The main task of technical committees is to prepare International Standards. Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

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.

ISO 10555-1 was prepared by Technical Committee ISO/TC 84, Devices for administration of medicinal products and intravascular catheters.

This second edition cancels and replaces the first edition which has been technically revised.

ISO 10555 consists of the following parts, under the general title *Intravascular catheters — Sterile and single-use catheters*:

— *Part 1: General requirements*

— *Part 2: Angiographic catheters:*

— *Part 3: Central venous catheters*

— *Part 4: Balloon dilatation catheters*

— *Part 5: Over-needle peripheral catheters*

Attention is drawn to ISO 11070, which will specify requirements for accessory devices for use with intravascular catheters.

Intravascular catheters — Sterile and single-use catheters —

Part 1: General requirements

1 Scope

This part of ISO 10555 specifies general requirements for intravascular catheters, supplied in the sterile condition and intended for single use, for any application.

lt does not apply to intravascular catheter accessories, which will be covered by a separate Standard.

This standard does not address coating performance.

2 Normative references

The following referenced documents are indispensable for the application 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 594-1:1986, *Conical fittings with a 6 % (Luer) taper for syringes, needles and certain other medical equipmen t - Part 1: General requirements*

ISO 594-2:1991, *Conical fittings with a 6 % (Luer) taper for syringes, needles and certain other medical equipment - Part 2: Lock fittings*

ISO 7886-1:1993,: *Sterile hypodermic syringes for single use - Part 1: Syringes for manual use*

3 Terms and definitions

For the purposes of this document, the terms and definitions apply:

3.1
intravascular catheter
tubular device, single or multilumen, designed to be partially or totally inserted or implanted into the cardiovascular system for diagnostic and/or therapeutic purposes

3.2
distal end
end of the catheter inserted furthest into the Patient

3.3
proximal end; access end
end of the catheter to which connection can be made

3.4
hub
connector(s) at the proximal end of the catheter which may either be integral with the catheter or be capable of being securely fitted to the proximal end of the catheter

3.5
effective length, *l*
l; Length of the catheter, or pre- and post-hydration lengths of hydratable catheters that can be inserted into the body (see Figure 1)

3.6
outside diameter
maximum specified diameter of the catheter or pre- and post-hydration maximum diameters of hydratable catheters that can be inserted into the vessel

3.7
junction
the joining of one tube or more tubes, where the assembly of the tubes provide mechanical support in tension/compression during clinical use

EXAMPLE A strain relief bonded to a hub provides no mechanical support in tension/compression.

3.8
hydratable intravascular catheter:
intravascular catheter consisting of a material that manifests clinically significant hydration when subjected to an aqueous medium

3.9
post-hydration
state of a hydratable intravascular catheter after immersion in appropriate aqueous medium at (37 ± 2) ℃ for a clinically appropriate period of time and maximum 2 h

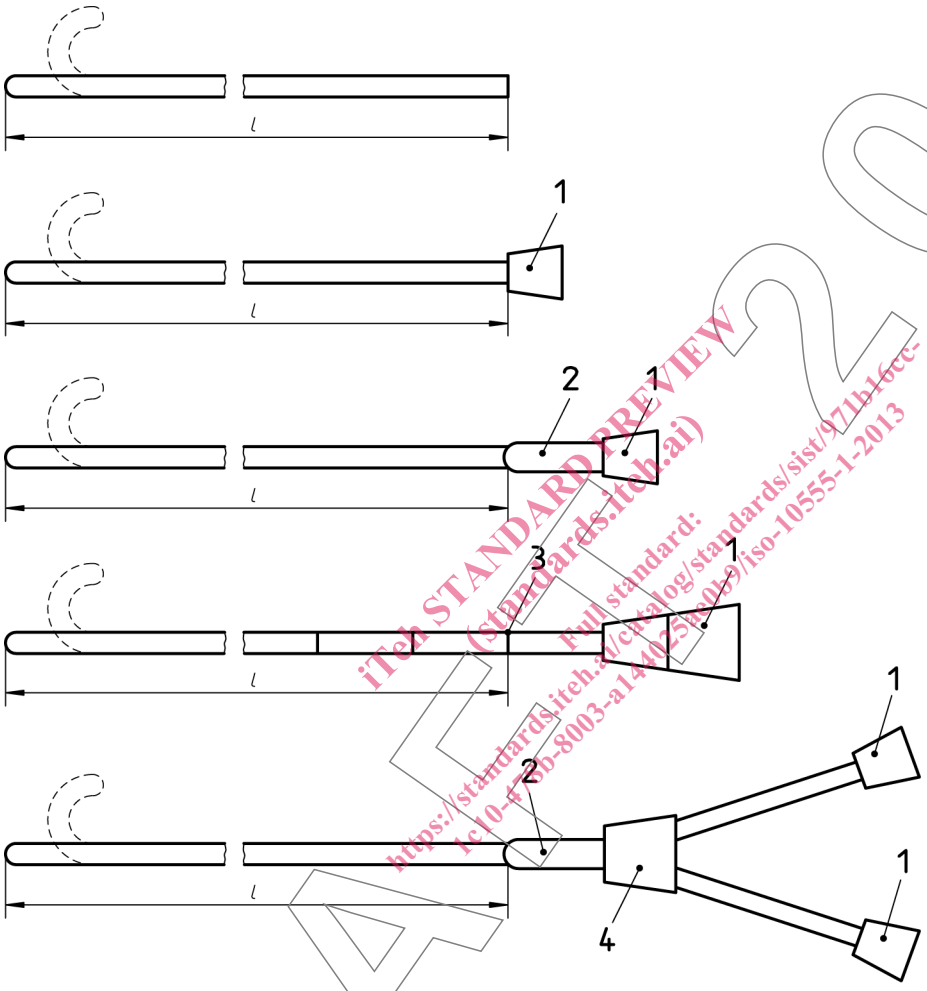
3.10
clinically significant hydration
hydrated state in which either the post-hydration effective length is greater than the pre-hydration effective length by more than 1 % of the effective length, or the post-hydration outside diameter is greater than the pre-hydration outside diameter by 10 % or more

3.11
antithrombotic and/or antimicrobial features
any material added to a catheter, to modify properties of the catheter

EXAMPLE Coatings or materials that may be physically and/or chemically bonded to the surface, impregnated into the catheter surface or compounded as a constituent of the catheter material.

3.12
power injector
rapid injection of fluid at high pressure for diagnostic purposes

EXAMPLE Angiography, computed tomography, MRI, flouroscopy etc.



Key

l = effective length
1 catheter hub
2 catheter strain reinforcement
3 length mark
4 junction

Figure 1 – Examples of effective length of catheters

4 Requirements

4.1 General

The catheter shall have been sterilized by an appropriate validated method, and shall comply with 4.2 to 4.7 in the sterile condition.

4.2 Biocompatibility

The catheter shall be free from biological hazard.

NOTE See ISO 10993-1 for the selection of appropriate test methods.

4.3 Surface

When examined by normal or corrected to normal vision, with a minimum x 2,5 magnification the external surface of the effective length of the catheter shall appear free from extraneous matter.

The external surface of the effective length of the catheter, including the distal end, shall be free from process and surface defects which could cause trauma to vessels during use.

If the catheter is lubricated, the lubricant shall not be visible as drops of fluid on the external surface when the catheter is examined under normal or corrected to normal vision.

The tip should be appropriately finished to minimize trauma to the vessels.

4.4 Corrosion resistance

When tested in accordance with the method given in Annex A, metallic components of the catheter intended for fluid path contact shall show no signs of corrosion.

4.5 Peak force at break

When tested in accordance with the method given in Annex B, the peak force at break of each test piece shall be as given in Table 1.

4.6 Freedom from leakage

4.6.1 The hub or connection fitting assembly or any other part of the catheter shall not leak liquid when tested in accordance with the method given in Annex C.

For hydratable intravascular catheters, this requirement shall be met in both the pre- and post-hydration states.

4.6.2 Air shall not leak into the hub assembly during aspiration when tested in accordance with the method given in Annex D.

For hydratable intravascular catheters, this requirement shall be met in both the pre- and post-hydration states.

Table 1 — Peak force at break of catheter test pieces

Smallest outside diameter of tubular portion of test piece	***Minimum force at break***

mm	*N*
≥ 0,55 < 0,75	3
≥ 0,75 < 1,15	5
≥ 1,15 < 1,85	10
≥ 1,85	15
NOTE This part of ISO 10555 does not specify requirements for peak force at break for tubing of less than 0,55 mm outside diameter (prehydration outside diameter for hydratable intravascular catheters) or for distal tip and its junction to the shaft tube. These values should be determined by the manufacturer based on risk assessment.	

4.7 Hubs

If the catheter is supplied with either an integral or a separate hub, it shall be a female hub that shall comply with ISO 594-1 and ISO 594-2.

4.8 Flowrate

For devices for which flow rate is defined, when tested in accordance with Annex E, the flow rate for each lumen shall be minimum 80 % of that stated by the manufacturer for catheters of nominal outside diameter less than I,0 mm or minimum 90 % of that stated by the manufacturer for catheters of nominal outside diameter I,0 mm or greater.

This part of ISO 10555 does not specify requirements for flowrate, but if the flowrate through hydratable catheters is determined, it shall be determined in post-hydration states.

4.9 Power injection

A catheter may be indicated for power injection if the probability of the burst pressure (see Annex F) being less than the pressure at the maximum pressure in the catheter as measured at the maximum rated flowrate (see Annex G) is less than XX at 95% confidence level.

In determining the suitability of a catheter for power injection, it should be assured that the product burst pressure will exceed the pressures present in the catheters at a maximum flow conditions as determined by Annexes F and G.

4.10 Side Holes

The design, number and positioning of side holes should be such as to minimize adverse effects on the catheter and trauma to the tissues.

5 Designation of nominal size

The nominal size of the catheter shall be designated as specified in 5.1 and 5.2.

5.1 Outside diameter

Unless otherwise specified in the International Standard for a particular type of catheter, the outside diameter shall be expressed as the nominal dimension in millimetres, rounded upwards to the nearest 0,01, 0,05 or 0,1 mm.