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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

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Foreword

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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 document 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).

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This document was prepared by Technical Committee ISO/TC 84, *Devices for administration of medicinal products and catheters*, 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 third edition cancels and replaces the second edition (ISO 10555-1:2013), which has been technically revised. It also incorporates the amendment ISO 10555-1:2013/Amd 1:2017.

The main changes are as follows:

— added definitions for “inside diameter”, “gauge length”, and “coating” in Clause 3;

— added clarification on requirements (Clause 4) related to:

  — peak tensile force (revised the NOTE in Table 1);

  — leakage during pressurization: option for air pressure test (Annex I);

  — power injection burst pressure.

— added new requirements (Clause 4) related to:

  — risk approach;

  — usability engineering;

  — shelf life;

  — packaging system;

  — simulated use, kink and torque;

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  - coating integrity, particulate;
  - distal tip stiffness.
- removed the requirements on side holes and distal tip;
- added text on “Nominal inside diameter for some applications” (Clause 5);
- added test details in the instructions for use for power injection (Clause 6);
- added reporting of maximum, minimum, standard deviation for variable data analysis in test reports;
- clarified “conditioning time” and “gauge length” (Annex B);
- clarified “minimum outside pressure requirement” (Annex D);
- introduced alternative test method using constant flowrate source (Annex G);
- replaced Figure H.1 in previous version with the new Table H.1;
- added new Annex I for alternative leakage under pressurization using air pressure;
- added new Annex J for rationale.

A list of all parts in the ISO 10555 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.

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Intravascular catheters — Sterile and single-use catheters —

Part 1: General requirements

1 Scope

This document specifies general requirements for intravascular catheters, supplied sterile and intended for single use, for any application.

This document does not apply to intravascular catheter accessories, e.g. those covered by ISO 11070.

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.

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

ISO 10993-1, *Biological evaluation of medical devices — Part 1: Evaluation and testing within a risk management process*

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ISO 11607-1, *Packaging for terminally sterilized medical devices — Part 1: Requirements for materials, sterile barrier systems and packaging systems*

ISO 14971, *Medical devices — Application of risk management to medical devices*

ISO 15223-1, *Medical devices — Symbols to be used with information to be supplied by the manufacturer — Part 1: General requirements*

ISO 80369-7, *Small-bore connectors for liquids and gases in healthcare applications — Part 7: Connectors for intravascular or hypodermic applications*

IEC 62366-1, *Medical devices — Part 1: Application of usability engineering to medical devices*

3 Terms and definitions

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

ISO and IEC maintain terminology databases for use in standardization at the following addresses:

— ISO Online browsing platform: available at https://www.iso.org/obp

— IEC Electropedia: available at https://www.electropedia.org/

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

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

3.3
distal end configuration
shape of the catheter which is designed to facilitate its manual manipulation through the vascular system and the placement and anchoring of the distal tip in the chosen location

3.4
proximal end
access end
end of the catheter to which connection to another device can be made

3.5
hub
connector(s) at the *proximal end* (3.4) of the catheter which can either be integral with the catheter or be capable of being securely fitted to the *proximal end* (3.4) of the catheter

3.6
effective length
working length
usable length
length of the catheter, or pre- and *post-hydration* (3.11) lengths of hydratable catheters, that can be inserted into the body

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Note 1 to entry: See Figure 1 where "*l*" is denoted as effective length.

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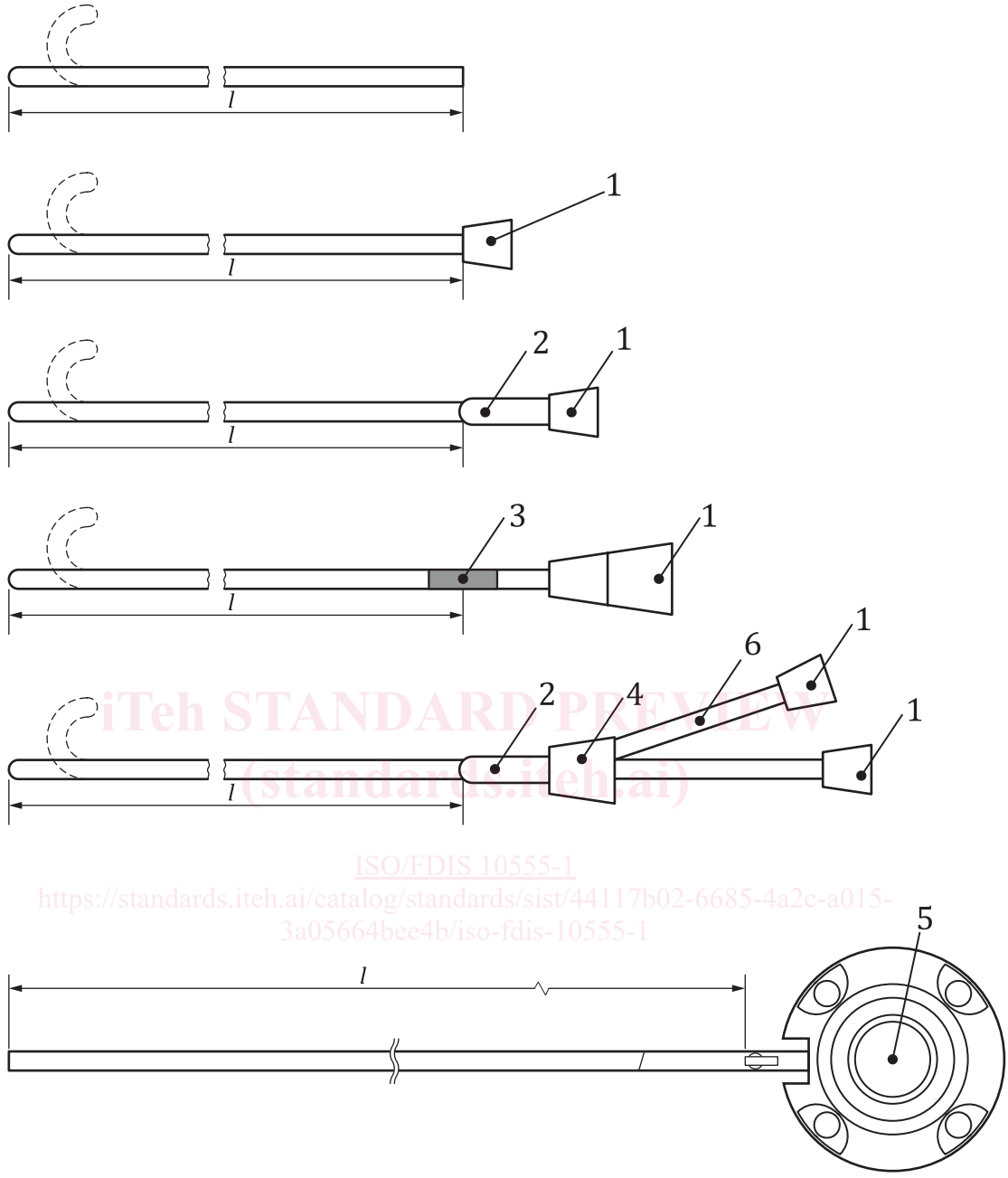

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Key

l effective length
1 catheter hub
2 catheter strain reinforcement
3 length mark
4 junction
5 pre-connected port
6 sidearm

Figure 1 — Examples of effective length of catheters

3.7
outside diameter
largest diameter of the catheter or pre- and *post-hydration* (3.11) largest diameters of hydratable catheters over the *effective length* (3.6)

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3.8
inside diameter
for a lumen intended to deliver other devices, the largest diameter that can pass through a catheter

Note 1 to entry: See Annex J for additional information.

3.9
junction
joint
fixed connection
joining of one tube or more tubes with another tube or component where the assembly provides mechanical support in tension/compression during clinical use

3.10
hydratable intravascular catheter
intravascular catheter consisting of a material which, when subjected to an aqueous medium, results in an increase of more than 1 % of the effective length or 10 % or more of the *outside diameter* (3.7) of the effective length in *post-hydration* (3.11) state compared to pre-hydration

3.11
post-hydration
state of a *hydratable intravascular catheter* (3.10) after immersion in aqueous medium at (37 ± 2) °C for a minimum of 2 h or a shorter time upon appropriate clinical justification

3.12
power injection
injection of an imaging contrast agent with a constant-pressure source or constant-flowrate source capable of generating pressures greater than or equal to 689 kPa

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3.13
primary packaging
packaging, which has direct contact with the device and/or maintains sterility

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3.14
secondary packaging
packaging designed to contain one or more *primary packages* (3.13) and/or accessories

3.15
gauge length
length of the test piece between the grips of the tensile testing apparatus that elongates significantly during testing

Note 1 to entry: See Figure B.1.

Note 2 to entry: See Annex J for additional information.

3.16
coating
substance or material with any different property (e.g. antimicrobial, lubricity, antithrombogenicity) than the natural surface of the substrate that is intentionally added to cover the substrate

Note 1 to entry: The coating can partially or fully cover the substrate surface. Liquid lubricant is not considered as coating.

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4 Requirements

4.1 Risk approach

Risk analysis, risk evaluation, risk control, evaluation of residual risk acceptability shall be performed in accordance with ISO 14971.

NOTE See Annex J for additional information.

4.2 Usability engineering

A usability engineering program shall be developed and implemented in accordance with IEC 62366-1, which shall include addressing use risks and tests and/or assessments as part of the design verification and validation.

NOTE See Annex J for additional information.

4.3 Sterilization

The devices shall be sterilized by a validated method.

The devices shall fulfil the requirements specified in 4.4 to 4.18 after being sterilized by a sterilization cycle representative of the final manufacturing process.

NOTE See applicable clause(s) of the ISO 17665 series, ISO 11135 and the ISO 11137 series for appropriate methods of sterilization.

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4.4 Shelf life

The impact of aging on product performance shall be considered based on risk assessment in order to support the shelf life.

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4.5 Detectability

Parts of the catheter shall be detectable by X-ray or by other means (e.g. ultra-sound, MRI, etc.) if required as determined by the risk assessment.

Detectability shall be demonstrated by an appropriate test method (see, e.g. ASTM F640-20 or DIN 13273-7).

4.6 Biocompatibility

The catheter shall be free from biological hazard in accordance with the appropriate testing in ISO 10993-1.

4.7 Surface

When examined by normal or corrected to normal vision and with a minimum x2,5 magnification the external surface of the catheter shall appear free from foreign matter.

The external surface of the effective length of the catheter, including the distal end, shall be free from surface defects which could cause embolic risks or trauma to vessels.

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.

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4.8 Corrosion resistance

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

4.9 Peak tensile force

Every section of the catheter shall be tested for peak tensile force in accordance with Annex B. Table 1 specifies the minimum peak tensile force for different sized tubular test pieces. Testing can be done on the complete device or different sections; however, minimum peak tensile force shall meet the requirements as specified in Table 1. See Figure 2 for examples of catheter sections and determination of effective outside diameter.

This document does not specify requirements for peak tensile force for tubing of less than 0,55 mm outside diameter (prehydration outside diameter for hydratable intravascular catheters). For those cases, the tensile test should be performed in accordance with Annex B and the peak tensile force shall be determined by the manufacturer based on risk assessment.

For a distal tip with a junction to the shaft tube, the peak tensile force shall be determined by the manufacturer based on risk assessment. For a distal tip of less than 3 mm with a junction for which a tensile test is not practical, the test method and requirements shall be determined by the manufacturer based on risk assessment.

For a distal tip of length less than 3 mm without a junction to the shaft tube, the tensile test is not required.

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For a distal tip of length equal to or more than 3 mm without a junction to the shaft tube, the peak tensile force shall be determined by the manufacturer based on risk assessment.

The forces experienced during clinical use may be greater than the values listed in Table 1, e.g. the expected forces applied to a delivery system during clinical use to access the intended location, to deploy the device, or to withdraw the system. If the forces experienced during clinical use are determined by the manufacturer to be greater than the values listed in Table 1, the acceptance criteria for the peak tensile force of each test piece shall be as determined by the manufacturer based on risk assessment.

NOTE See Annex J for additional information.

Table 1 — Peak tensile force of catheter test pieces

Effective outside diameter range of tubular portion of test piece mm	**Minimum peak tensile force** *N*
≥ 0,55 < 0,75	3
≥ 0,75 < 1,15	5
≥ 1,15 < 1,85	10
≥ 1,85	15

NOTE 1 Values listed in Table 1 are not based on clinical data or forces that have been determined to be clinically-relevant. However, these values have been historically used to support functional performance and can be acceptable with appropriate rationale.

NOTE 2 See Annex J for additional information.

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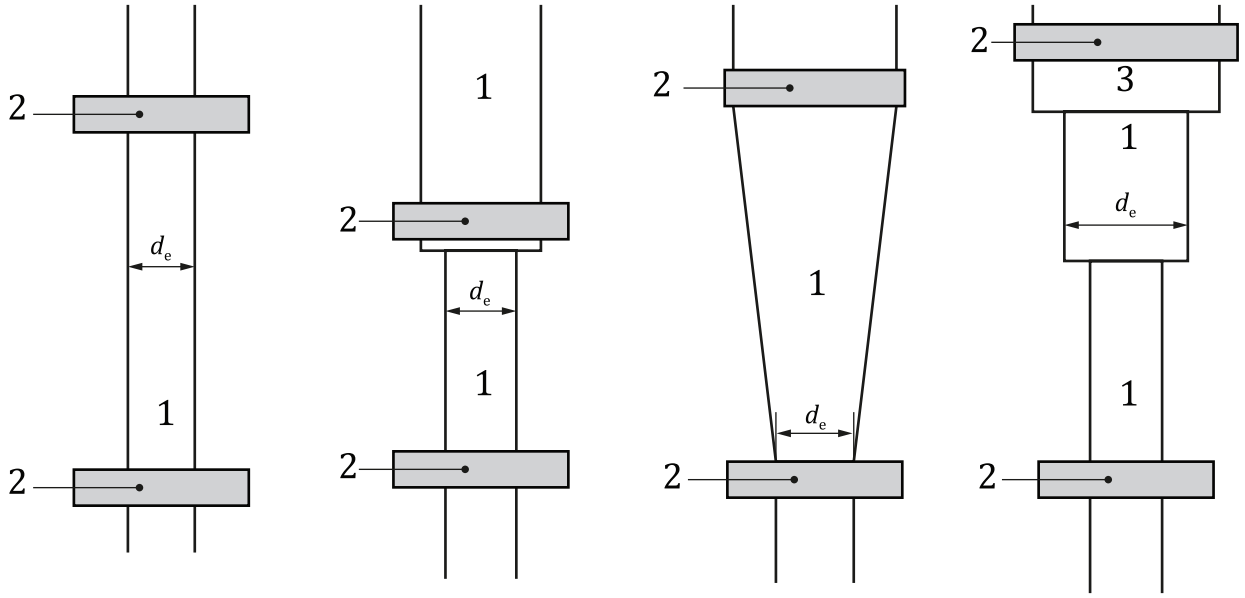

a) Straight tubing section | **b) Junction between two sections of tubing** | **c) Tapered tubing section** | **d) Multiple junctions tested simultaneously**

Key

d_e effective outside diameter
1 tubing
2 grip
3 hub

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Figure 2 — Illustration of effective outside diameter

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NOTE See Annex J for additional information.

4.10 Freedom from leakage during pressurization

If subjected to liquid pressure during intended use, the hub or connection fitting assembly or any other part of the catheter shall not leak when tested using either liquid pressure as set out in Annex C or air pressure in accordance with Annex I. If a sample fails the air leakage under water test (see Annex I), it is acceptable to retest the sample using the method in Annex C.

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

NOTE See Annex J for additional information.

4.11 Freedom from leakage during aspiration

If subjected to aspiration during intended use, 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.

4.12 Hubs

If the catheter is supplied with either an integral or a separate hub, it shall be a female hub in accordance with ISO 80369-7.

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4.13 Flowrate

For devices for which flow rate is specified, when tested in accordance with Annex E for all catheter lumen indicated for gravity delivery of fluid, the flow rate for each lumen shall be a minimum of 80 % of that stated in the information supplied by the manufacturer for catheters of nominal outside diameter less than 1,0 mm or a minimum of 90 % of that stated in the information supplied by the manufacturer for catheters of nominal outside diameter equal to or greater than 1,0 mm.

If the flowrate through hydratable catheters is determined, it shall be determined in post-hydration states.

4.14 Power injection burst pressure

If a catheter lumen is indicated for power injection, it shall be tested in accordance with Annexes F and G. In Annex G, either test A or B may be used. The lumen burst pressure (in accordance with Annex F) shall exceed the peak pressure present in that lumen (in accordance with Annex G) when flowing at the maximum flowrate stated in the information supplied by the manufacturer.

If desired, each fluid path may be divided into zones along its length and different pressure specifications can be assigned for each zone. A rationale shall be provided supporting why the pressure specification for each zone is sufficient. For example, analysis and/or empirical testing can be an appropriate justification for lower pressures (than that used in accordance with Annex G) in distal zones.

NOTE See Annex J for additional information.

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4.15 Packaging system

Design of sterile barrier systems and packaging systems for the catheter shall be in accordance with the requirements of ISO 11607-1.

NOTE ISO 11607-2 describes the process development and validation requirements for forming, sealing and assembly processes and addresses controls during normal operations.

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4.16 Simulated use, kink and/or torque testing to consider depending on device design, intended use, and risk analysis

Simulated use testing, kink testing, and torque strength testing shall be considered (if applicable) for devices that are intended to traverse anatomy that might expose it to multiple modes of mechanical loading in sufficiently challenging clinical setting (e.g. guide catheters intended to reach neurovasculature, PTA balloons intended to be used in a contralateral antegrade approach) based on risk assessment.

— For simulated use testing, the device shall perform as intended in a sufficiently challenging simulated clinical setting without damage that could affect functionality or safety of the device.

— For kink testing, the device shall resist kinking when used in a sufficiently challenging radius of curvature.

— For torque testing, the device shall resist damage that can affect functionality or safety of the device when subjected to sufficiently challenging torque.

Clinical use conditions or scientific justification shall be used to establish methods and criteria depending on device design, intended use, and risk analysis.

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4.17 Coating integrity and/or particulate testing to consider depending on device design, intended use, and risk analysis

Coating integrity and/or particulate testing shall be considered, if applicable, for devices that include a coating which might pose a safety risk if inadvertently removed from the device.

— For coating integrity testing, representative sections of the coated device surface shall be examined under magnification (e.g. light microscopy, scanning electron microscopy) before and after simulated use to evaluate the amount of material that is removed during simulated use. Non-disruptive visualization enhancements (e.g. liquid dyes) may be used where appropriate.

— For particulate testing, particulate generated after simulated use shall be quantitatively characterized using appropriate means (e.g. light obscuration counting, scanning electron microscopy), across a range of equivalent spherical diameters determined by the manufacturer based on intended use and risk assessment.

Clinical use conditions or scientific justification shall be used to establish methods and criteria depending on device design, intended use, and risk analysis. Either test may be sufficient for lower risk application, while both tests may be applicable for high-risk applications.

NOTE AAMI TIR42 lists several examples of acceptable particulate generation measurement methods.

4.18 Distal tip stiffness testing to consider for neurovascular applications

Distal tip stiffness testing shall be considered for devices that are intended to be used in the neurovasculature, based on risk assessment.

Clinical use conditions or scientific justification shall be used to establish methods and criteria depending on device design, intended use, and risk analysis.

NOTE See Annex K for additional information.

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5 Designation of nominal size

5.1 Nominal outside diameter

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

For devices which are not round by design, the size shall be designated by the dimension of the largest axis. Where relevant, manufacturers may choose to report additional information regarding the device profile, such as the dimension of the second axis for an oval shape.

5.2 Nominal inside diameter

For a neurovascular or coronary device intended to deliver other devices (not included with it), the inside diameter shall be expressed as the nominal dimension in mm, rounded downwards to the nearest 0,01 mm or 0,1 mm.

NOTE See Annex J for additional information.

5.3 Nominal effective length

The nominal effective length shall be expressed in millimetres for effective lengths of less than 100 mm.

The nominal effective length shall be expressed in millimetres or centimetres for effective lengths of 100 mm or more.

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