SLOVENSKI STANDARD
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Žilni katetri - Sterilni žilni katetri za enkratno uporabo - 1. del: Splošne zahteve (ISO 10555-1:2023)

Intravascular catheters - Sterile and single-use catheters - Part 1: General requirements (ISO 10555-1:2023)

Intravaskuläre Katheter - Sterile Katheter zur einmaligen Verwendung - Teil 1: Allgemeine Anforderungen (ISO 10555-1:2023)

Cathéters intravasculaires - Cathéters stériles et non réutilisables - Partie 1: Exigences générales (ISO 10555-1:2023)

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Intravascular catheters - Sterile and single-use catheters - Part 1: General requirements (ISO 10555-1:2023)

Cathéters intravasculaires - Cathéters stériles et non réutilisables - Partie 1: Exigences générales (ISO 10555-1:2023)

Intravaskuläre Katheter - Sterile Katheter zur einmaligen Verwendung - Teil 1: Allgemeine Anforderungen (ISO 10555-1:2023)

This European Standard was approved by CEN on 24 November 2023.

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EUROPEAN COMMITTEE FOR STANDARDIZATION
COMITÉ EUROPÉEN DE NORMALISATION
EUROPÄISCHES KOMITEE FÜR NORMUNG

CEN-CENELEC Management Centre: Rue de la Science 23, B-1040 Brussels

Contents

Page

European foreword **3**

European foreword

This document (EN ISO 10555-1:2023) has been prepared by Technical Committee ISO/TC 84 "Devices for administration of medicinal products and catheters" 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of an identical text or by endorsement, at the latest by May 2024, and conflicting national standards shall be withdrawn at the latest by May 2024.

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Endorsement notice

The text of ISO 10555-1:2023 has been approved by CEN as EN ISO 10555-1:2023 without any modification.

INTERNATIONAL STANDARD

ISO 10555-1

Third edition
2023-11

Intravascular catheters — Sterile and single-use catheters —

Part 1: General requirements

Cathéters intravasculaires — Cathéters stériles et non réutilisables —

Partie 1: Exigences générales

Reference number
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Contents

Page

Foreword ..... **v**

1 Scope **1**

2 Normative references **1**

3 Terms and definitions **1**

4 Requirements **5**
4.1 Risk approach 5
4.2 Usability engineering 5
4.3 Sterilization 5
4.4 Shelf life 5
4.5 Detectability 5
4.6 Biocompatibility 5
4.7 Surface 5
4.8 Corrosion resistance 6
4.9 Peak tensile force 6
4.10 Freedom from leakage during pressurization 7
4.11 Freedom from leakage during aspiration 7
4.12 Hubs 7
4.13 Flowrate 8
4.14 Power injection burst pressure 8
4.15 Packaging system 8
4.16 Simulated use, kink and/or torque testing to consider depending on device design, intended use, and risk analysis 8
4.17 Coating integrity and/or particulate testing to consider depending on device design, intended use, and risk analysis 9
4.18 Distal tip stiffness testing to consider for neurovascular applications 9

5 Designation of nominal size **9**
5.1 Nominal outside diameter 9
5.2 Nominal inside diameter 9
5.3 Nominal effective length 9

6 Information to be supplied with the catheter **10**
6.1 General 10
6.2 Marking on the device and/or primary packaging 10
6.3 Instructions for use 11
6.4 Marking on the secondary packaging 11

Annex A (normative) **Test method for corrosion resistance** **12**

Annex B (normative) **Method for determining peak tensile force** **13**

Annex C (normative) **Test method for liquid leakage under pressure** **16**

Annex D (normative) **Test method for air leakage into hub assembly during aspiration** **18**

Annex E (normative) **Determination of flowrate through catheter** **20**

Annex F (normative) **Test for burst pressure under static conditions** **22**

Annex G (normative) **Power injection tests for flowrate and device pressure (only for products indicated for power injection)** **25**

Annex H (informative) **Units of measurement systems other than those specified in this document** **30**

Annex I (normative) **Test method for air leakage under water** **32**

Annex J (informative) **Rationale and guidance** **34**

Annex K (informative) **Test methods for distal tip stiffness for neurovascular applications** **41**

Bibliography **43**

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 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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For an explanation of 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 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;

  - 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.

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.

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*

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

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

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