



BSI Standards Publication

Intravascular catheters — Sterile and single-use catheters

Part 1: General requirements

National foreword

This British Standard is the UK implementation of EN ISO 10555-1:2023. It is identical to ISO 10555-1:2023. It supersedes BS EN ISO 10555-1:2013+A1:2017, which is withdrawn.

The UK participation in its preparation was entrusted to Technical Committee CH/84, Catheters and syringes.

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

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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

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of an identical text or by endorsement, at the latest by May 2024, and conflicting national standards shall be withdrawn at the latest by May 2024.

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

This document supersedes EN ISO 10555-1:2013.

Any feedback and questions on this document should be directed to the users' national standards body/national committee. A complete listing of these bodies can be found on the CEN website.

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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.

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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 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