



BSI Standards Publication

Intravascular catheters — Sterile and single-use catheters

Part 4: Balloon dilatation catheters

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National foreword

This British Standard is the UK implementation of EN ISO 10555-4:2023. It is identical to ISO 10555-4:2023. It supersedes BS EN ISO 10555-4:2013, which is withdrawn.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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Published by BSI Standards Limited 2023

ISBN 978 0 539 20328 8

ICS 11.040.25

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This British Standard was published under the authority of the Standards Policy and Strategy Committee on 31 December 2023.

Amendments/corrigenda issued since publication

Date	Text affected
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EUROPÄISCHE NORM

November 2023

ICS 11.040.25

Supersedes EN ISO 10555-4:2013

English Version

Intravascular catheters - Sterile and single-use catheters - Part 4: Balloon dilatation catheters (ISO 10555-4:2023)

Cathéters intravasculaires - Cathéters stériles et non
réutilisables - Partie 4: Cathéters de dilatation à
ballonnets (ISO 10555-4:2023)

Intravaskuläre Katheter - Sterile Katheter zur
einmaligen Verwendung - Teil 4:
Ballondilatationskatheter (ISO 10555-4:2023)

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

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European foreword

This document (EN ISO 10555-4:2023) 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of an identical text or by endorsement, at the latest by May 2024, and conflicting national standards shall be withdrawn at the latest by May 2024.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 10555-4:2013.

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.

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, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Republic of North Macedonia, Romania, Serbia, Slovakia, Slovenia, Spain, Sweden, Switzerland, Türkiye and the United Kingdom.

Endorsement notice

The text of ISO 10555-4:2023 has been approved by CEN as EN ISO 10555-4:2023 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 10555-4:2013), which has been technically revised.

The main changes are as follows:

- added a definition for balloon rated burst pressure (RBP) (see [3.2](#));
- added a definition (see [3.3](#)), requirement (see [4.4.5](#)), and created test method (see [Annex E](#)) for crossing profile;
- added guidance on endpoint of deflation period (see [Annex C](#));
- defined effective length of the balloon (see [3.4](#));
- expanded radio-detectability to include detectability by x-ray or by other means (see [4.2](#));
- within designation of nominal size, added the minimum inner diameter of the introducer, guide catheter, sheath, etc. that can be used with the catheter (see [4.3](#));
- added requirement (see [4.4.6](#)) and test method (see [Annex F](#)) for balloon removal without damage after inflation and deflation;
- added annex for rationale of changes and guidance (see [Annex G](#)).

A list of all parts in the ISO 10555 series can be found on the ISO website.

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Intravascular catheters — Sterile and single-use catheters —

Part 4: Balloon dilatation catheters

1 Scope

This document specifies requirements for balloon dilatation catheters supplied sterile and intended for single use.

This document does not specify requirements for vascular stents (see ISO 25539-2).

NOTE Guidance on the selection of balloon materials is given in [Annex G](#).

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 10555-1:2023, *Intravascular catheters — Sterile and single-use catheters — Part 1: General requirements*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 10555-1 and the following 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

balloon dilatation catheter

intravascular catheter fitted with a balloon, which is introduced into an artery or vein to dilate a part or parts of the vascular system

3.2

balloon rated burst pressure

RBP

pressure at which the balloon bursts or leaks with an appropriate safety margin

3.3

crossing profile

maximum outer diameter found between the proximal end of the uninflated balloon and the distal tip of the catheter

3.4

effective length of the balloon

length of the balloon intended to treat the lesion