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STN	**Intravaskulárne katétre Sterilné intravaskulárne katétre na jednorazové použitie Časť 4: Balónikové dilatačné katétre (ISO 10555-4: 2023)**	**STN EN ISO 10555-4** 85 5825

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

Táto norma obsahuje anglickú verziu európskej normy.
This standard includes the English version of the European Standard.

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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)

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

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of an identical text or by endorsement, at the latest by May 2024, and conflicting national standards shall be withdrawn at the latest by May 2024.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

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Endorsement notice

The text of ISO 10555-4:2023 has been approved by CEN as EN ISO 10555-4:2023 without any modification.

INTERNATIONAL STANDARD

ISO 10555-4

Third edition
2023-11

Intravascular catheters — Sterile and single-use catheters —

Part 4: Balloon dilatation catheters

Cathéters intravasculaires — Cathéters stériles et non réutilisables —

Partie 4: Cathéters de dilatation à ballonnets

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ISO copyright office
CP 401 • Ch. de Blandonnet 8
CH-1214 Vernier, Geneva
Phone: +41 22 749 01 11
Email: copyright@iso.org
Website: www.iso.org

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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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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.

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.

INTERNATIONAL STANDARD **ISO 10555-4:2023(E)**

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*