SLOVENSKI STANDARD
SIST EN ISO 10555-4:2024

01-marec-2024

Nadomešča:
SIST EN ISO 10555-4:2013

Žilni katetri - Sterilni žilni katetri za enkratno uporabo - 4. del: Balonski katetri za širjenje žil (ISO 10555-4:2023)

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

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

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

Ta slovenski standard je istoveten z: **EN ISO 10555-4:2023**

ICS:

11.040.25	Injekcijske brizge, igle in katetri	Syringes, needles an catheters

SIST EN ISO 10555-4:2024 **en,fr,de**

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN ISO 10555-4

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)

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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

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of an identical text or by endorsement, at the latest by May 2024, and conflicting national standards shall be withdrawn at the latest by May 2024.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

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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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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.