SLOVENSKI STANDARD
oSIST prEN ISO 10555-5:2026

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Žilni katetri - Sterilni žilni katetri za enkratno uporabo - 5. del: Periferni intravenski katetri z notranjo iglo (ISO/DIS 10555-5:2026)

Intravascular catheters - Sterile and single-use catheters - Part 5: Over-needle peripheral intravenous catheters (ISO/DIS 10555-5:2026)

Intravaskuläre Katheter - Sterile Katheter zur einmaligen Verwendung - Teil 5: Periphere Katheter mit innen liegender Kanüle (ISO/DIS 10555-5:2026)

Cathéters intravasculaires - Cathéters stériles et non réutilisables - Partie 5: Cathéters intraveineux périphériques à aiguille interne (ISO/DIS 10555-5:2026)

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ICS:

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

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DRAFT International Standard

ISO/DIS 10555-5

Intravascular catheters — Sterile and single-use catheters —

Part 5: Over-needle peripheral intravenous catheters

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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 documents 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 intravascular catheters*.

This third edition cancels and replaces the second edition (ISO 10555-5:2013), which has been technically revised.

The main changes are as follows:

— xxx xxxxxxx xxx xxxx:

Drafting note: list will be inserted after DIS stage.

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

Attention is drawn to ISO 11070, which specifies requirements for accessory devices for use with intravenous catheters, and to ISO 14972, which specifies requirements for sterile obturators for use with over-needle peripheral intravenous catheters.

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 5: Over-needle peripheral intravenous catheters

1 Scope

This document specifies requirements for over-needle peripheral intravenous catheters, intended for accessing the peripheral venous system, supplied in the sterile condition and intended for single use.

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 80369-7, *Small-bore connectors for liquids and gases in healthcare applications — Part 7: Connectors for intravascular or hypodermic applications*

ISO 9626, *Stainless steel needle tubing for the manufacture of medical devices*

ISO 10555-1, *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.

NOTE See Figure 1 for visual representation of definitions with exception of 3.7.

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
over-needle peripheral intravenous catheter
catheter designed for the introduction or withdrawal of liquids or devices into or from the peripheral venous system

3.2
needle
assembly comprising at least a *needle tube* (3.3) attached to, and communicating with, a *needle hub* (3.4)

3.3
needle tube
rigid tube with one end sharpened with a bevel to facilitate entry into body tissue

3.4
needle hub
fitting attached to the *needle tube* (3.3)