



SLOVENSKI STANDARD SIST EN ISO 8871-5:2025

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Nadomešča:
SIST EN ISO 8871-5:2017

Deli iz elastomera za parenteralne farmacevtske oblike - 5. del: Funkcionalne zahteve in preskušanje (ISO 8871-5:2025)

Elastomeric parts for parenterals and for devices for pharmaceutical use - Part 5: Functional requirements and testing (ISO 8871-5:2025)

Elastomere Teile für Parenteralia und für Geräte zur pharmazeutischen Verwendung - Teil 5: Funktionelle Anforderungen und Prüfung (ISO 8871-5:2025)

Éléments en élastomère pour administration parentérale et dispositifs à usage pharmaceutique - Partie 5: Exigences fonctionnelles et essais (ISO 8871-5:2025)

Ta slovenski standard je istoveten z: **EN ISO 8871-5:2025**

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ICS:

11.040.20	Transfuzijska, infuzijska in injekcijska oprema	Transfusion, infusion and injection equipment
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SIST EN ISO 8871-5:2025

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EUROPEAN STANDARD
NORME EUROPÉENNE
EUROPÄISCHE NORM

EN ISO 8871-5

March 2025

ICS 11.040.20

Supersedes EN ISO 8871-5:2016

English Version

**Elastomeric parts for parenterals and for devices for
pharmaceutical use - Part 5: Functional requirements and
testing (ISO 8871-5:2025)**

Éléments en élastomère pour administration
parentérale et dispositifs à usage pharmaceutique -
Partie 5: Exigences fonctionnelles et essais (ISO 8871-
5:2025)

Elastomere Teile für Parenteralia und für Geräte zur
pharmazeutischen Verwendung - Teil 5: Funktionelle
Anforderungen und Prüfung (ISO 8871-5:2025)

This European Standard was approved by CEN on 22 March 2025.

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EUROPEAN COMMITTEE FOR STANDARDIZATION
COMITÉ EUROPÉEN DE NORMALISATION
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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 8871-5:2025) has been prepared by Technical Committee ISO/TC 76 "Transfusion, infusion and injection, and blood processing equipment for medical and pharmaceutical use" 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 September 2025, and conflicting national standards shall be withdrawn at the latest by September 2025.

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 8871-5:2016.

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 8871-5:2025 has been approved by CEN as EN ISO 8871-5:2025 without any modification.



International Standard

ISO 8871-5

Elastomeric parts for parenterals and for devices for pharmaceutical use —

Part 5: Functional requirements and testing

*Éléments en élastomère pour administration parentérale et
dispositifs à usage pharmaceutique —*

Partie 5: Exigences fonctionnelles et essais

**Third edition
2025-03**

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ISO 8871-5:2025(en)

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ISO 8871-5:2025(en)

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 76, *Transfusion, infusion and injection, and blood processing equipment for medical and pharmaceutical use*, 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 8871-5:2016), which has been technically revised.

The main changes are as follows:

- "aqueous solution tightness" has been replaced with "dye solution tightness";
- definition for fragmentation has been clarified;
- definitions for "filling volume" and "nominal volume" have been added;
- information on the fragmentation test and new information on the fragment size have been added;
- "pore size of 0,5 µm" has been replaced with "pore size of maximum 5,0 µm" to be aligned with ISO 11608-3;
- clarification on the fragments counting measurements has been added;
- "dye solution tightness" from the self-sealing test has been removed;
- "solution of methylene blue" has been replaced by "appropriate dye solution" and new information on the dye solution;
- "methylene blue" has been replaced by "dye solution";
- references to USP <788> and USP <1207> have been added.

A list of all parts in the ISO 8871 series can be found on the ISO website.