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STN	**Dielce z elastomérov na parenterálne použitie a pre farmaceutické prístroje Časť 5: Funkčné požiadavky a skúšanie (ISO 8871-5: 2025)**	**STN EN ISO 8871-5** 85 5225

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

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

Táto norma bola oznámená vo Vestníku ÚNMS SR č. 07/25

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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
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Contents

Page

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of an identical text or by endorsement, at the latest by September 2025, and conflicting national standards shall be withdrawn at the latest by September 2025.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.

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Endorsement notice

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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
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Contents

Page

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 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.

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.

Introduction

The elastomeric parts specified in the ISO 8871 series are produced from rubber and thermoplastic elastomers (TPE). These pharmaceutical use closures are used in combination with vials and many times in conjunction with piercing devices. There are three functional parameters which are important to the piercing process. These are penetrability, fragmentation and self-sealing. The three functional tests described in this document can be used as a reference method for testing closures that are pierced using injection needles made from metal. In addition, the dye solution tightness test can be used to verify the effectiveness of the sealing of a specific closure/vial combination.

International Standard **ISO 8871-5:2025(en)**

Elastomeric parts for parenterals and for devices for pharmaceutical use —

Part 5:
Functional requirements and testing

1 Scope

This document specifies requirements and test methods for functional parameters of closures used in combination with vials and when pierced by an injection needle.

NOTE Functional testing with spikes is specified in ISO 8536-2, ISO 8536-6, ISO 8362-1 and ISO 8362-4.

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 7864, *Sterile hypodermic needles for single use — Requirements and test methods*

ISO 8362-1, *Injection containers and accessories — Part 1: Injection vials made of glass tubing*

ISO 8362-3, *Injection containers and accessories — Part 3: Aluminium caps for injection vials*

ISO 8362-4, *Injection containers and accessories — Part 4: Injection vials made of moulded glass*

ISO 8362-6, *Injection containers and accessories — Part 6: Caps made of aluminium-plastics combinations for injection vials*