



SLOVENSKI STANDARD
oSIST prEN ISO 8871-5:2024
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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/DIS 8871-5:2024)

Elastomeric parts for parenterals and for devices for pharmaceutical use - Part 5: Functional requirements and testing (ISO/DIS 8871-5:2024)

Elastomere Teile für Parenteralia und für Geräte zur pharmazeutischen Verwendung - Teil 5: Funktionelle Anforderungen und Prüfung (ISO/DIS 8871-5:2024)

Éléments en élastomère pour administration parentérale et dispositifs à usage pharmaceutique - Partie 5: Exigences fonctionnelles et essais (ISO/DIS 8871-5:2024)

Ta slovenski standard je istoveten z: prEN ISO 8871-5

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ICS:

11.040.20	Transfuzijska, infuzijska in injekcijska oprema	Transfusion, infusion and injection equipment
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oSIST prEN ISO 8871-5:2024

en,fr,de



DRAFT International Standard

ISO/DIS 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

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ISO/DIS 8871-5:2024(en)

Contents

	Page
Foreword	iv
Introduction	v
1 Scope	1
2 Normative references	1
3 Terms and definitions	1
4 Requirements	2
4.1 Penetrability.....	2
4.2 Fragmentation.....	2
4.3 Self-sealing and dye solution tightness.....	2
4.4 Dye solution tightness.....	2
5 Preparation of elastomeric closures for testing	2
5.1 Sampling.....	2
5.2 Cleaning.....	2
5.3 Sterilization.....	3
Annex A (normative) Test for penetrability	4
Annex B (normative) Test for fragmentation	5
Annex C (normative) Test for self-sealing and dye solution tightness	7
Annex D (normative) Test for dye solution tightness	9
Bibliography	11

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Foreword

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The committee responsible for this document is ISO/TC 76, *Transfusion, infusion and injection, and blood processing equipment for medical and pharmaceutical use*.

This third edition cancels and replaces the second edition (8871-5:2016), which has been technically revised. The main changes are as follows:

- replaced "aqueous solution tightness" with "dye solution tightness",
- additional definition for fragmentation,
- additional information on the fragmentation test and new information on the fragment size,
- replaced "pore size of 0,5 µm" with "pore size of maximum 5,0 µm",
- added USP <788> and USP <1207> references.

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