
**Injection containers and
accessories —**

Part 2:
Closures for injection vials

AMENDMENT 1

Réipients et accessoires pour produits injectables —

Partie 2: Bouchons pour flacons

AMENDEMENT 1

ISO 8362-2:2015/Amd 1:2022

<https://standards.iteh.ai/catalog/standards/sist/01ffc0d6-037f-47a2-8b1a-73a392a5abcb/iso-8362-2-2015-amd-1-2022>



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ISO copyright office
CP 401 • Ch. de Blandonnet 8
CH-1214 Vernier, Geneva
Phone: +41 22 749 01 11
Email: copyright@iso.org
Website: www.iso.org

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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/SS S02, *Transfusion equipment*, in accordance with the Agreement on technical cooperation between ISO and CEN (Vienna Agreement).

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Injection containers and accessories —

Part 2: Closures for injection vials

AMENDMENT 1

Normative references

Delete the following reference:

ISO 48, *Rubber, vulcanized or thermoplastic — Determination of hardness (hardness between 10 IRHD and 100 IRHD)*

Replace the reference to ISO 7619-1 with the following:

ISO 48-4, *Rubber, vulcanized or thermoplastic — Determination of hardness — Part 4: Indentation hardness by durometer method (Shore hardness)*

Replace the reference to ISO 8871-5:2005 with the following:

ISO 8871-5:2016, *Elastomeric parts for parenterals and for devices for pharmaceutical use — Part 5: Functional requirements and testing*

4.1, Table 1

Replace Table 1 with the following: <https://standards.iteh.ai/catalog/standards/sist/01ffc0d6-037f-47a2-8b1a-73a392a5abcb/iso-8362-2-2015-amd-1-2022>

Table 1 — Dimensions of injection closures

Dimensions in millimetres

Type	Nominal size	d_1	d_2	d_3	d_4	h_1	h_2	h_3	h_4	Injection vials	
		$\pm 0,15$	max.	$\pm 0,2$	$\pm 0,2$	min.	$\pm 0,2$	min.	min.	ISO 8362-1	ISO 8362-4
A	13	7,5	5	12,5	-	6,2	2,0	2,0	1,5	2 R and 4 R	-
	20	13,2	10	18,8	-	8,5	3,3	2,0	1,5	6 R to 100 R	5 H to 100 H
B	13	7,4	5	12,5	7,6	6,2	2,0	2,0	1,5	-	2 I to 10 I
	20	13,0	10	18,8	13,3	8,5	3,3	2,0	1,5	-	6 H to 100 H

7.2.1

Replace the text with the following:

The hardness agreed between manufacturer and user shall not differ from the nominal value by more than ± 5 Shore A when tested in accordance with ISO 48-4 on a special test specimen.

7.2.2

Replace the text with the following:

The requirements of ISO 8871-5:2016, 4.1, shall apply.

7.2.3

Replace the text with the following:

The requirements of ISO 8871-5:2016, 4.2, shall apply.

7.2.4

Replace the text with the following:

The requirements of ISO 8871-5:2016, 4.3, shall apply.

7.2.5

Replace the subclause with the following:

7.2.5 Aqueous solution tightness

The requirements of ISO 8871-5:2016, 4.4, shall apply. If the test specimen conforms with 7.2.4, the requirements of this subclause have also been met and separate testing according to this subclause is not needed.

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