INTERNATIONAL STANDARD

ISO 8362-2

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AMENDMENT 1
2022-08

Injection containers and accessories —

Part 2: Closures for injection vials

AMENDMENT 1

Récipients et accessoires pour produits injectables —
Partie 2: Bouchons pour flacons
AMENDEMENT 1

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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:

Table 1 — Dimensions of injection closures

Dimensions in millimetres

Type	Nominal size	d_1 ±0,15	d_2 max.	d_3 ±0,2	d_4 ±0,2	h_1 min.	h_2 ±0,2	h_3 min.	h_4 min.	Injection vials	
										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.

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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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