INTERNATIONAL STANDARD

ISO 11040-4

Third edition
2015-04-01

AMENDMENT 1
2020-02

Prefilled syringes —

Part 4: Glass barrels for injectables and sterilized subassembled syringes ready for filling

AMENDMENT 1

Seringues préremplies —

Partie 4: Cylindres en verre pour produits injectables et seringues pré-assemblées stérilisées préremplissables

AMENDEMENT 1

Reference number
ISO 11040-4:2015/Amd.1:2020(E)

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Published in Switzerland

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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.*

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Prefilled syringes —

Part 4:
Glass barrels for injectables and sterilized subassembled syringes ready for filling

AMENDMENT 1

Normative references

Replace the references to ISO 594-1 and ISO 594-2 with the following:

ISO 80369-7, *Small-bore connectors for liquids and gases in healthcare applications — Part 7: Connectors for intravascular or hypodermic applications*

Delete footnote 1).

Replace the reference to ISO 7886-1:1993 with the following:

ISO 7886-1:2017, *Sterile hypodermic syringes for single use — Part 1: Syringes for manual use*

Add the following reference:

ISO 21748:2017, *Guidance for the use of repeatability, reproducibility and trueness estimates in measurement uncertainity estimation*

4.2.1

Replace the text with the following:

Repeatability shall be evaluated for each test method in each laboratory.

Delete EXAMPLE.

5.1.1, second paragraph, second sentence

Replace the references "ISO 594-1" and "ISO 594-2" with "ISO 80369-7".

5.1.1, NOTE, third sentence

Replace the reference "ISO 594 series" with "ISO 80369-7".

5.1.1, NOTE, fourth sentence

Replace the reference "The ISO 594 series" with "ISO 80369-7".

5.1.1, third paragraph, third sentence

Replace the reference "ISO 594" with "ISO 80369-7".

5.1.1, third paragraph, last sentence

Replace the reference "ISO 594:1986" with "ISO 80369-7".

5.1.1, fourth paragraph

Replace the reference "ISO 594" with "ISO 80369-7".

5.1.2, Table 1

Replace header, "Finger flange", third line, under "d_3", second column "*nom.*" with "*tol.*".

5.2, second paragraph

Replace the reference "ISO 594-1" with "ISO 80369-7".

6.5.1.3

Replace the reference ISO 7886-1:1993 with "ISO 7886-1:2017".

6.5.2.2

Replace the third list item with the following:

— actual needle length should be in accordance with ISO 7864 (see *l* in ISO 7864:2016, Figure 2).

6.5.2.2, second paragraph

Replace the paragraph with the following:

When there are particular requirements on needle tip height from the flange or the shoulder, the dimension should be agreed upon between the manufacturer and the customer.

6.5.3.4

Replace the references "ISO 594-1, ISO 594-2" with "ISO 80369-7".

A.2.2, Title

Replace the reference "ISO 594-1" with "ISO 80369-7".