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**Prefilled syringes —**

Part 4:

**Glass barrels for injectables and  
sterilized subassembled syringes  
ready for filling**

**AMENDMENT 1**  
**(standards.iteh.ai)**  
*Seringues préremplies —*

*Partie 4: Cylindres en verre pour produits injectables et seringues pré-  
assemblées stérilisées préremplissables*  
<https://standards.iteh.ai/catalog/standards/sist/33a00d40-ec5c-4f23-a3c0-36fa91a01155/ISO-11040-4-2015-Amd.1-2020>  
**AMENDMENT 1** 1015-amd-1-2020



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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 documents 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](http://www.iso.org/directives)).

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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 uncertainty 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".

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

### 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".

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### 6.5.1.3

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

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### 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".

*A.2.3, Title*

Replace the reference "ISO 594-2" with "ISO 80369-7".

*A.2.3, first paragraph*

Replace the reference "ISO 594-2" with "ISO 80369-7".

*Figure B.1, Key, footnote b*

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

*Figure B.2, Key, footnote b*

Replace the reference "ISO 594-2" with "ISO 80369-7".

*D.2.1*

Replace the text with the following:

The sample preparation of particulate matter determination is based on USP <788><sup>[40]</sup> and Ph. Eur. 2.9.19<sup>[29]</sup>.

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*D.2.3.11, Formula (D.2)*

Replace " $V_a$  is the nominal volume of the syringe (ml)" with " $V_a$  is the nominal volume of each portion analysed (ml)".

*G.3.3.1, first list item*

Replace the reference "ISO 594-2" with "ISO 80369-7".

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