INTERNATIONAL STANDARD

ISO 11040-1

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Prefilled syringes —

Part 1: Glass cylinders for dental local anaesthetic cartridges

Seringues préremplies —

Partie 1: Tubes en verre pour cartouches dentaires d'anesthésie locale

Reference number
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Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

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).

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For an explanation on the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the WTO principles in the Technical Barriers to Trade (TBT) see the following URL: Foreword - Supplementary information.

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

This second edition cancels and replaces the first edition (ISO 11040-1:1992), which has been technically revised with the following changes:

— including glass cylinders of 2,2 ml size;

— amending the requirements on performance and marking;

— editorial revision of this part of ISO 11040-1.

ISO 11040 consists of the following parts, under the general title *Prefilled syringes*:

— *Part 1: Glass cylinders for dental local anaesthetic cartridges*

— *Part 2: Plungers stoppers for dental local anaesthetic cartridges*

— *Part 3: Seals for dental local anaesthetic cartridges*

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

— *Part 5: Plunger stoppers for injectables*

— *Part 6: Plastics barrels for injectables*

— *Part 7: Packaging systems for sterilized subassembled syringes ready for filling*

— *Part 8: Requirements and test methods for finished prefilled syringes*

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Prefilled syringes —

Part 1:
Glass cylinders for dental local anaesthetic cartridges

1 Scope

This part of ISO 11040 specifies the design, dimensions, materials, performance and test methods for glass cylinders for dental local anaesthetic cartridges with a volume of 1,7 ml, 1,8 ml and 2,2 ml intended for single use only.

NOTE 1 Cartridges of 1,0 ml size are described in ISO 11499.

It applies to primary packs used in direct contact with a drug.

NOTE 2 The potency, purity, stability and safety of a drug during its manufacture and storage can be strongly affected by the nature and performance of the primary pack.

2 Normative references

The following documents, in whole or in part, are normatively referenced in this document and are indispensable for its application. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 720, *Glass — Hydrolytic resistance of glass grains at 121 degrees C — Method of test and classification*

ISO 4802–1, *Glassware — Hydrolytic resistance of the interior surfaces of glass containers — Part 1: Determination by titration method and classification*

ISO 4802–2, *Glassware — Hydrolytic resistance of the interior surfaces of glass containers — Part 2: Determination by flame spectrometry and classification*

3 Dimensions and designation

3.1 Dimensions

The dimensions of the glass cylinder shall be as shown in Figure 1.

Variations of the design of the truncated cone are allowed, if at the same time, the following conditions are fulfilled:

— truncated cone has the height of the neck length (5 ± 0,2) mm;

— stated tolerances of the neck opening are maintained;

— diameter of the neck opening at the inner end and at the cone may be a maximum of 0,3 mm smaller than the top (3,15 ± 0,15) mm.

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