International Standard

ISO 11040-3

Third edition
2025-11

Prefilled syringes —

Part 3: Seals for dental local anaesthetic cartridges

Seringues préremplies —

Partie 3: Rondelles d'étanchéité pour cartouches dentaires d'anesthésie locale

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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 of the voluntary nature of standards, the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT), see www.iso.org/iso/foreword.html.

This document was prepared by Technical Committee ISO/TC 76, *Transfusion, infusion and injection, and blood processing equipment for medical and pharmaceutical use.*

This third edition cancels and replaces the second edition (ISO 11040-3:2012), which has been technically revised.

The main changes are as follows:

— the terms and definitions clause (Clause 3) has been added and subsequent clauses have been renumbered;

— the normative references have been updated;

— Figure 1 and Table 1 have been updated;

— opening diameter and aluminium thickness dimensions have been added in Table 1;

— the term “user” was replaced by “manufacturer” and “customer” for clarity;

— “coated” was added in the material description in 7.1;

— disc was replaced by liner;

— ISO 13926-3 has been added to the bibliography.

A list of all parts of ISO 11040 series can be found on the ISO website.

Any feedback or questions on this document should be directed to the user’s national standards body. A complete listing of these bodies can be found at www.iso.org/members.html.

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Introduction

The elastomeric parts specified in the ISO 11040 series are produced from rubber and thermoplastic elastomers (TPE).

Primary packaging components are an integral part of medicinal products. Therefore, the principles of current good manufacturing practices (cGMP) apply to the manufacturing of these components.

Principles of cGMP are described in ISO 15378 or in the GMP Guidelines published by the European Community and the United States of America.

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Prefilled syringes —

Part 3:
Seals for dental local anaesthetic cartridges

1 Scope

This document specifies the shape, dimensions, material, performance requirements and labelling of seals for dental local anaesthetic cartridges intended for single use only.

NOTE The potency, purity, stability and safety of a medicinal product during its manufacture and storage can be significantly affected by the nature and performance of the primary packaging.

2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

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

ISO 3302-1, *Rubber — Tolerances for products — Part 1: Dimensional tolerances*

ISO 7885:2010, *Dentistry — Sterile injection needles for single use*

ISO 8871-1, *Elastomeric parts for parenterals and for devices for pharmaceutical use — Part 1: Extractables in aqueous autoclavates*

ISO 8871-4, *Elastomeric parts for parenterals and for devices for pharmaceutical use — Part 4: Biological requirements and test methods*

ISO 8871-5:2025, *Elastomeric parts for parenterals and for devices for pharmaceutical use — Part 5: Functional requirements and testing*

ISO 8872, *Aluminium caps and aluminium/plastic caps for infusion bottles and injection vials — General requirements and test methods*

ISO 11040-1, *Prefilled syringes — Part 1: Glass cylinders for dental local anaesthetic cartridges*

ISO 11040-2, *Prefilled syringes — Part 2: Plunger stoppers for dental local anaesthetic cartridges*

3 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

ISO and IEC maintain terminology databases for use in standardization at the following addresses:

— ISO Online browsing platform: available at https://www.iso.org/obp

— IEC Electropedia: available at https://www.electropedia.org/

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3.1
customer
business entity which purchases primary packaging components and conducts further processing as appropriate

3.2
liner
disc
mono-layer or double-layer of the elastomer component of a container, which seals the end of the container through which the medicinal product is accessed

3.3
seal
combination of a mono-layer or double-layer *liner* (3.2) with an aluminium cap

3.4
manufacturer
business entity which performs or is responsible for the manufacturing of the primary packaging components, including further processing, as appropriate

3.5
purified water
water obtained by a suitable process and contains no added substance

4 Classification

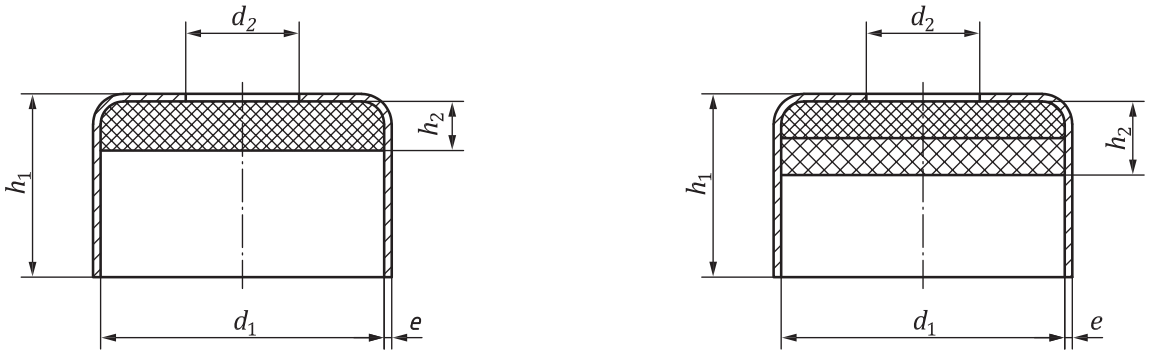
Seals shall be classified as follows:

— type A: seals with a mono-layer liner;

— type B: seals with a double-layer liner.

5 Shape and dimensions

5.1 The shape and dimensions of seals shall be as shown in Figure 1 and given in Table 1.



a) Type A: Seal with a mono-layer liner **b) Type B: Seal with a double-layer liner**

Figure 1 — Shapes of seals for dental local anaesthetic cartridges

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