

INTERNATIONAL STANDARD

ISO
11040-3

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Prefilled syringes —

Part 3:

Aluminium caps for dental local anaesthetic
cartridges

Seringues préremplies —

*Partie 3: Capsules en aluminium pour cartouches dentaires d'anesthésie
locale*



Reference number
ISO 11040-3:1993(E)

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.

Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

International Standard ISO 11040-3 was prepared jointly by Technical Committees ISO/TC 76, *Transfusion, infusion and injection equipment for medical use* and ISO/TC 106, *Dentistry*.

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 and discs for dental local anaesthetic cartridges*
- Part 3: *Aluminium caps for dental local anaesthetic cartridges*
- Part 4: *Glass barrels for injectables*
- Part 5: *Plungers for injectables*

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Prefilled syringes —

Part 3:

Aluminium caps for dental local anaesthetic cartridges

1 Scope

This part of ISO 11040 specifies the design, dimensions, material, performance requirements and marking of aluminium or aluminium alloy caps (called "aluminium caps" herein) with disc laid in which serve to seal the glass cylinder of prefilled dental local anaesthetic cartridges.

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

NOTE 1 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 reference

The following standard contains provisions which, through reference in this text, constitute provisions of this part of ISO 11040. At the time of publication, the edition indicated was valid. All standards are subject to revision, and parties to agreements based on this part of ISO 11040 are encouraged to investigate the possibility of applying the most recent edition of the standard indicated below. Members of IEC and ISO maintain registers of currently valid International Standards.

ISO 8872:1988, *Aluminium caps for transfusion, infusion and injection bottles — General requirements and test methods*.

3 Dimensions and designation

3.1 Dimensions

The dimensions of aluminium caps for prefilled cartridges shall be as shown in figure 1.

3.2 Designation

Aluminium caps are designated according to type: the two types A and B are illustrated in figure 1. The designation is expressed as the number and part of this International Standard followed by the type letter.

EXAMPLE

A type A (i.e. centre hole) aluminium cap with the requirements laid down in this part of ISO 11040 is designated

Aluminium cap ISO 11040-3 - A

4 Requirements

General requirements for aluminium caps shall be in accordance with ISO 8872.

In addition, in order to protect the aluminium cap from mercury, the cap shall be anodized or suitably lacquered.

5 Testing

Testing shall be in accordance with ISO 8872.

6 Packaging

Packaging shall be in accordance with ISO 8872.

7 Marking

Marking shall be in accordance with ISO 8872.