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STANDARD

ISO
11040-2

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Prefilled syringes —

Part 2:

Plungers and discs for dental local anaesthetic
cartridges

Seringues préremplies —

*Partie 2: Bouchons-pistons et rondelles d'étanchéité pour cartouches
dentaires d'anesthésie locale*



Reference number
ISO 11040-2:1994(E)

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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.

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 11040-2 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 and plastics rods for injectables*

Annexes A, B and C form an integral part of this part of ISO 11040.

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Prefilled syringes —

Part 2:

Plungers and discs for dental local anaesthetic cartridges

1 Scope

This part of ISO 11040 specifies the design, dimensions, materials, performance, requirements, marking and test methods for plungers and discs for dental local anaesthetic cartridges intended for single use only.

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 references

The following standards contain provisions which, through reference in this text, constitute provisions of this part of ISO 11040. At the time of publication, the editions indicated were 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 editions of the standards indicated below. Members of IEC and ISO maintain registers of currently valid International Standards.

ISO 48:1994, *Rubber, vulcanized or thermoplastic — Determination of hardness (hardness between 10 IRHD and 100 IRHD)*.

ISO 3302:1990, *Rubber — Dimensional tolerances for use with products*.

ISO 7864:1993, *Sterile hypodermic needles for single use*.

ISO 7886-1:1993, *Sterile hypodermic syringes for single use — Part 1: Syringes for manual use*.

ISO 8362-5:—¹⁾, *Injection containers for injectables and accessories — Part 5: Freeze drying closures for injection vials*.

ISO 8871:1990, *Elastomeric parts for aqueous parenteral preparations*.

ISO 9997:1990, *Dental cartridge syringes*.

ISO 11040-1:1992, *Prefilled syringes — Part 1: Glass cylinders for dental local anaesthetic cartridges*.

ISO 11040-3:1993, *Prefilled syringes — Part 3: Aluminium caps for dental local anaesthetic cartridges*.

3 Classification of types

3.1 Plungers

Plungers shall be classified as follows:

Type A: Plungers without cavities;

Type B: Plungers with one cavity;

Type C: Plungers with two cavities.

1) To be published.