International

ISO 11040-3

Prefilled syringes —

Part 3: Seals for dental local anaesthetic cartridges

Seringues préremplies —

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

Third edition
2025-11

Reference number
ISO 11040-3:2025(en)

ISO copyright office
CP 401 • Ch. de Blandonnet 8
CH-1214 Vernier, Geneva
Phone: +41 22 749 01 11
Email: copyright@iso.org
Website: www.iso.org

Published in Switzerland

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).

ISO draws attention to the possibility that the implementation of this document may involve the use of (a) patent(s). ISO takes no position concerning the evidence, validity or applicability of any claimed patent rights in respect thereof. As of the date of publication of this document, ISO had not received notice of (a) patent(s) which may be required to implement this document. However, implementers are cautioned that this may not represent the latest information, which may be obtained from the patent database available at www.iso.org/patents. ISO shall not be held responsible for identifying any or all such patent rights.

Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

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.

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.