



**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**

This is a preview of ISO 11040-3:2025. [Click here to purchase the full version from the ANSI store.](#)



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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](http://www.iso.org/members.html).

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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.