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**Pen systems —**

**Part 3:**

**Seals for pen-injectors for medical use**

*Systèmes de stylos-injecteurs —*

*Partie 3: Joints pour stylos-injecteurs à usage médical*



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## Foreword

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International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 2.

The main task of technical committees is to prepare International Standards. 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.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights.

ISO 13926-3 was prepared by Technical Committee ISO/TC 76, *Transfusion, infusion and injection, and blood processing equipment for medical and pharmaceutical use*.

ISO 13926 consists of the following parts, under the general title *Pen systems*:

- *Part 1: Glass cylinders for pen-injectors for medical use*
- *Part 2: Plunger stoppers for pen-injectors for medical use*
- *Part 3: Seals for pen-injectors for medical use*

## Introduction

Primary packaging components made of elastomeric materials are an integral part of medicinal products. As such, the principles of current Good Manufacturing Practices (cGMP) are applicable to the manufacturing of these components.

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

# Pen systems —

## Part 3: Seals for pen-injectors for medical use

### 1 Scope

This part of ISO 13926 specifies the shape, dimensions, material, performance requirements and labelling of seals for pen-injectors for medical use.

**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 referenced documents are indispensable for the application 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 3302 (all parts), *Rubber — Tolerances for products*

ISO 7619-1, *Rubber, vulcanized or thermoplastic — Determination of indentation hardness — Part 1: Durometer method (Shore hardness)*

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 8871-5:2005, *Elastomeric parts for parenterals and for devices for pharmaceutical use — Part 5: Functional requirements and testing*

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

ISO 11608-3, *Needle-based injection systems for medical use — Requirements and test methods — Part 3: Finished containers<sup>1)</sup>*

ISO 13926-1, *Pen systems — Part 1: Glass cylinders for pen-injectors for medical use*

ISO 13926-2, *Pen systems — Part 2: Plunger stoppers for pen-injectors for medical use*

### 3 Classification

Seals shall be classified as follows:

- type A: seals with a mono-layer disc;
- type B: seals with a double-layer disc.

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1) To be published.