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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*

Reference number
ISO 13926-3:2012(E)



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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 phamaceutical 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.