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Pen-injectors for medical use —

Part 4: Requirements and test methods for electronic and electromechanical pen-injectors

Stylos-injecteurs à usage médical —

Partie 4: Exigences et méthodes d'essai pour stylos-injecteurs électroniques et électro-mécaniques

Reference number
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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.

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 11608-4 was prepared by Technical Committee ISO/TC 84, *Devices for administration of medicinal products and intravascular catheters*.

ISO 11608 consists of the following parts, under the general title *Pen-injectors for medical use*:

— *Part 1: Pen-injectors — Requirements and test methods*

— *Part 2: Needles — Requirements and test methods*

— *Part 3: Finished cartridges — Requirements and test methods*

— *Part 4: Requirements and test methods for electronic and electromechanical pen-injectors*

Introduction

This part of ISO 11608 covers electro-mechanical driven injectors not covered by part 1 of ISO 11608. These injectors are mainly intended to administer medicinal products to humans. This part of ISO 11608 provides performance requirements regarding essential aspects of the design so that variations of such injectors are not unnecessarily restricted.

The sampling plans for inspection selected for this part of ISO 11608 are intended to verify, at a high confidence level, the manufacturer's ability to manufacture one “lot” of injectors that conforms to the critical product attributes. These sampling plans for inspection do not intend to replace the more general manufacturing quality systems practices widely used in production, e.g. the ISO 9000 series.

Materials to be used for the construction of these injectors are not specified, as their selection, to some extent, will depend upon the design, the intended use and the manufacturing process selected by the manufacturer. All materials used in these injectors which come in contact with the end-user must be non-toxic and biocompatible. In some countries, national regulations may exist and their requirements may supersede or add up to this part of ISO 11608.

In relation to specification limits and dose accuracy, the ISO directives (Part 2, A3 and A13) require that the VIM[1] and GUM[2] principles are used and incorporated in all future standards and future revisions of existing standards. The reorganization to be done in relation to this will not affect the technical content of the standards, and only the terminology shall be changed to correspond to VIM, and the principles shall be changed to correspond to GUM.

However, with this part of ISO 11608, ISO/TC 84 has decided to await the revision of the ISO 11608 series where the principles will be incorporated in all parts to conform to applicable requirements.