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Pen-injectors for medical use —

Part 1: Pen-injectors — Requirements and test methods

Stylos-injecteurs à usage médical —

Partie 1: Stylos-injecteurs — Exigences et méthodes d'essai

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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 3.

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 part of ISO 11608 may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights.

International Standard ISO 11608-1 was prepared by Technical Committee ISO/TC 84, *Medical devices for injections*.

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*

Annex A of this part of ISO 11608 is for information only.

Introduction

This part of ISO 11608 covers pen-injectors primarily intended for human use. It provides performance requirements regarding essential aspects, so that variations of design are not unnecessarily restricted.

The devices described in this part of ISO 11608 are designed to be used with devices described in ISO 11608-2 and ISO 11608-3.

It is recognized that interchangeability of the components (pen-injector, needle and cartridge) is desirable for some medicinal products and to be avoided for other medicinal products, and that future design may change the current concepts. Therefore, ISO 11608-2 and ISO 11608-3 encourage interchangeability by establishing certain specific requirements for interchangeable needles (Type A) and interchangeable cartridges (Type A) respectively.

Performance requirements are imposed on both Type A (interchangeable) and non-Type A needles and cartridges. Additional dimensional requirements are imposed on Type A needles and cartridges and hereby indirectly on pen-injectors intended for either Type A needles and/or Type A cartridges.

Information as to whether the components are interchangeable (Type A) or not should be given on the unit container.

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 pen-injectors that conforms to the critical product attributes. The sampling plans for inspection do not replace the more general manufacturing quality systems that appear in standards on quality systems, e.g. the ISO 9000 series.

Materials to be used for the construction are not specified, as their selection to some extent will depend upon the design, the intended use and the process of manufacture by individual manufacturers. All materials should be resistant to the medicinal product intended to be injected with the pen-injector.

In some countries national regulations exist, and their requirements may supersede or complement this part of ISO 11608.

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