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Second edition
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Needle-based injection systems for medical use — Requirements and test methods —

Part 3: Finished containers

Systèmes d'injection à aiguille pour usage médical — Exigences et méthodes d'essai —

Partie 3: Conteneurs prêts à l'emploi



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 11608-3 was prepared by Technical Committee ISO/TC 84, *Devices for administration of medicinal products and intravascular catheters*.

This second edition cancels and replaces the first edition (ISO 11608-3:2000), which has been technically revised.

ISO 11608 consists of the following parts, under the general title *Needle-based injection systems for medical use — Requirements and test methods*:

- *Part 1: Needle-based injection systems*
- *Part 2: Needles*
- *Part 3: Finished containers*
- *Part 4: Requirements and test methods for electronic and electromechanical pen-injectors*
- *Part 5: Automated functions*

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Introduction

This part of ISO 11608 is applicable to containers that are provided pre-filled, or that are to be filled by the user with medicinal products intended by the manufacturer to be used with needle-based injection systems (NIS), as covered by ISO 11608.

The previous edition of this part of ISO 11608 introduced the concept of interchangeability and the labelling designation of Type A (i.e. interchangeable) and non-Type A for needles and containers.

Since its publication, experience has shown that the complexity of these systems makes it very difficult to ensure functional compatibility as defined in this International Standard, particularly when products are made by different manufacturers and the design is not verified as a system. The "Type A" designation, therefore, does not represent adequate guidance to the user in making decisions on the compatibility of needles and containers with specific NIS. As such, the labelling designation of "Type A" has been removed.

The previous edition of this part of ISO 11608 also only addressed cartridges as the drug container. This was consistent with the scope of ISO 11608 (all parts), which was previously restricted to cartridge-based injection pens. The scope of the latest revision of ISO 11608 (all parts) has been expanded beyond pen injectors and now includes all NIS, resulting in additional possibilities for compatible containers, including syringes to be used with NIS, and potentially other containers not yet defined. In order to preserve this information, this part of ISO 11608 maintains those specifications, requirements and dimensions. It is important to stress that the design requirements related to system function have been maintained as a guide to assist manufacturers during the design phase in supporting the achievement of cross-platform compatibility. However, these design requirements are an insufficient replacement for system testing of the components and, where possible, direct communication and/or quality agreements between system component manufacturers. Given the patient convenience benefits associated with cross-platform compatibility, it is helpful if manufacturers of needles, containers and NIS label their products with the specific system components that have been tested and demonstrated to be functionally compatible.

For containers other than cartridges, this part of ISO 11608 can be used as a guide to understand the parameters and design criteria to be considered in the selection and/or design of containers that will be used with NIS. It provides performance requirements regarding essential aspects so that variations of design are not unnecessarily restricted.

The sampling plans for inspection selected for this part of ISO 11608 are intended for design verification at a high confidence level. The sampling plans for inspection do not replace the more general manufacturing quality systems that appear in standards on quality management systems, such as the ISO 9000 series and ISO 13485.

There are other international and national standards, guidance materials and, in some countries, national regulations that are applicable to medical devices and pharmaceuticals; their requirements might supersede or complement this part of ISO 11608. Developers and manufacturers of NIS are encouraged to investigate and determine if there are any other requirements relevant to the safety or marketability of their products.