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

Part 4: Needle-based injection systems containing electronics

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

Partie 4: Systèmes d'injection à aiguille contenant de l'électronique

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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.

The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular, the different approval criteria needed for the different types of ISO documents should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see www.iso.org/directives).

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. Details of any patent rights identified during the development of the document will be in the Introduction and/or on the ISO list of patent declarations received (see www.iso.org/patents).

Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

For an explanation of the voluntary nature of standards, the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT), see www.iso.org/iso/foreword.html.

This document was prepared by Technical Committee ISO/TC 84, *Devices for administration of medicinal products and catheters*, in collaboration with the European Committee for Standardization (CEN) Technical Committee CEN/TC 205, *Non-active medical devices,* in accordance with the Agreement on technical cooperation between ISO and CEN (Vienna Agreement).

This second edition cancels and replaces the first edition (ISO 11608-4:2006), which has been technically revised.

The main changes are as follows:

— this document has been revised in its entirety to include requirements from the IEC 60601 series that pertain to hand-held medical injectors.

A list of all parts in the ISO 11608 series can be found on the ISO website.

Any feedback or questions on this document should be directed to the user's national standards body. A complete listing of these bodies can be found at www.iso.org/members.html.

Introduction

Needle-based injection systems, including on-body delivery systems (OBDSs), containing electronics with or without software, are primarily intended to administer medicinal products to humans. Performance requirements regarding essential electrotechnical aspects have been selected with the intention not to restrict the Electronic Needle-based Injection System (NIS-E) design unnecessarily when applying the document.

The first edition of this document was limited to pen-injectors with electromechanical drive. Pen-injectors only equipped with electronics were covered in ISO 11608-1.

Materials used for construction are not specified in this document, as their selection will depend on the design, the intended use and the process of manufacture used by individual manufacturers.

There are other international and national standards and guidance publications and, in some countries, national regulations that are applicable to medical devices and pharmaceuticals. This document is applicable to NIS-E and specifies relevant aspects of IEC 60601-1:2005+AMD1:2012+AMD2:2020, IEC 60601-1-2:2014+AMD1:2020 and IEC 60601-1-11:2015+AMD1:2020 for this particular device type.

This document does not specify non-electrotechnical requirements and test methods for NISs when specified by ISO 11608-1.

Developers and manufacturers of NIS-Es are encouraged to investigate and determine whether there are any other requirements relevant to the safety or marketability of their NIS-Es. For example, this document should be used in conjunction with IEC 60601-1, IEC 60601-1-2 and IEC 60601-1-11. A risk-based approach is expected to be applied during the design, development, and manufacture of the product. Given the specific medicinal product intended use and environment, this might result in product-specific requirements and test methods that differ from what is outlined in this document.

This document is intended to be used for type testing (testing of the development result) of NIS-E. It is not intended to be used for batch release testing.

This document introduces the notion of Type X NIS-E and Type Y NIS-E. Type X NIS-E is a device type without any physical cabled connection to other devices. Type Y NIS-E has such connections. The electrical requirements in this document for Type X NIS-E is a subset of the requirements for Type Y NIS-E.