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

Part 1: Needle-based injection systems

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

Partie 1: Systèmes d'injection à aiguille

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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 fourth edition cancels and replaces the third edition (ISO 11608-1:2014), which has been technically revised.

The main changes are as follows:

— relocation of content to the other parts of the ISO 11608 series, as appropriate (see Figure 1);

— added language to address the case when a platform NIS is applied for different therapeutics or users;

— clarified that the “user” referenced in this document is the patient receiving the therapeutic, and not the health care professional who prescribes the medication (see Clause 1);

— defined “bolus”, and confirmed that this document is focused on bolus (fixed dose) delivery (not basal bolus), so as to distinguish from the definition in IEC 60601-2-24 (see Clause 1);

— clarified the references to ISO 13485, ISO 14971 and IEC 62366-1 (see 5.1.2, 5.3 and 5.4, respectively) and exclude any reference to an equivalent standard;

— elimination of the term “essential performance” and defined “primary functions” - those functions for which failure would “directly” result in “new and unacceptable harm”. This is to eliminate confusion with use of the term essential performance in IEC 60601-1 (see 5.7.2, Clause 7 and Annex H). Further, there is a focus on “unacceptable harm” and not just “risk”;

— clarification of the recommendations for sample sizes for primary functions (Clause 7), simplified the number of rules from 3 to 2 (see 7.4.2.1), and updated the recommended sample sizes (see Table 3), but confirmed that different sample sizes can be chosen, if justified [see Clause 9 g)];

— the rationale for different sample sizes for free fall testing between system designations A/B and C/D was clarified (see 10.3.1 and Annex A);

— differentiated lighting levels for user legibility – the ability of the user to read the labelling in normal use conditions (see 11.2) and inspection for defects (see 11.3);

— rationales in Annex A were expanded to address clauses throughout the document.

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

This document covers needle-based injection systems (referred to as NISs) intended for human use. It provides performance requirements and characteristics so that variations of design are not unnecessarily restricted. The document does not cover needle-free injectors.

Because of the anticipated variation in the designs of NISs, this document tends to specify the results of the design effort instead of the physical and construction requirements used as the basis for NIS design.

The ISO 11608 series deals with "hand-held" or "on-body" delivery systems (OBDSs). By hand-held, users (patients or caregivers) control and stabilize the NIS at the injection site during administration of a discrete volume. Delivery times for this type of NIS would, therefore, be limited to avoid instability and the potential for injection site trauma. For NISs with larger delivery volumes or physical properties requiring a longer time to deliver, OBDS might be more practical. The OBDS would likely exist as either "body-worn" (directly anchored to the body, e.g. using adhesive) or "patient-worn" (indirectly anchored, e.g. catheter attached to OBDS contained in a back-pack or pocket). In either configuration, the time or speed employed to deliver a discrete volume would be based upon tolerability or convenience rather than clinical relevance (e.g. medication efficacy) as would be the case with insulin patch pumps or traditional infusion pumps (e.g. IEC 60601-2-24, ISO 28620) associated with continuous delivery (e.g. insulin). However, while this document is not intended to directly apply to these pump products, it does contain requirements and tests methods that can be used to help design and evaluate them.

The ISO 11608 series includes requirements for design verification of the NIS's conformance with its design specification. The sampling plans, preconditioning criteria and other aspects of testing specified in these documents are intended to verify the design at a high confidence level. They are not intended to stipulate lot release acceptance criteria (AQL, *p*-content, probability, etc.) associated with a manufacturing process. The ISO 11608 series includes other aspects beyond dose accuracy. Finally, it develops the requirement for functional stability and offers additional statistical approaches (e.g. use of variable and attribute data) in satisfying the various NIS design verification requirements.

Figure 1 illustrates the correlations between the different parts in the ISO 11608 series and other applicable standards.

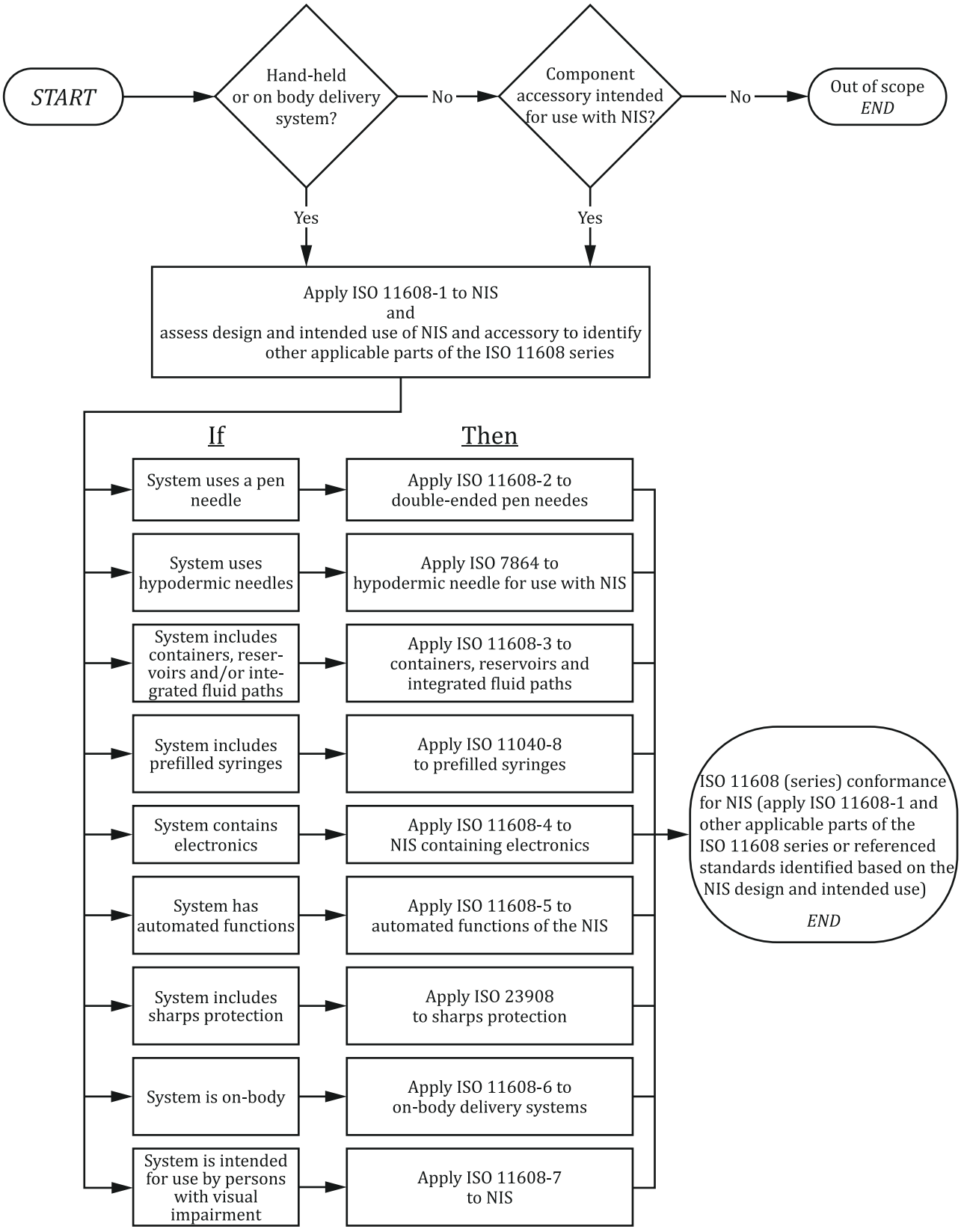

Figure 1 — ISO 11608 series road map

The design requirements related to system function are presented as to assist manufacturers during the design phase. However, these design requirements do not replace system testing of the components

and, where possible, direct communication and/or quality agreements between system component manufacturers.

Materials to be used for construction are not specified, 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, guidance publications and, in some countries, national regulations that are applicable to medical devices and pharmaceuticals. Developers and manufacturers of NISs are encouraged to investigate and determine whether there are any other requirements relevant to the suitability and safety of their products.

This document is written with the understanding that each system will be verified and validated for each therapeutic or medicinal product for which it is intended to be used. If the same system is able to, with no or minimal changes, deliver more than one therapeutic or medicinal product, due to the nature and uniqueness of the combination of the delivery system and therapeutic or medicinal product, it will be considered another product and each combination should be addressed individually in accordance with the requirements of this document. This does not preclude leveraging information and data across systems as long as there is sufficient information to support the unique combination under development.

Finally, manufacturers are expected to follow a risk-based approach during the design, development, and manufacture of the NIS. Given that each product can deliver different medicinal products and/or have a different intended use, this can result in product-specific requirements and test methods that differ from what is outlined in this document. It is expected that a risk management process is applied to justify and document:

— any exclusions/deviations from requirements, specifications, methods or limits contained in or referenced in this document when they are not directly applicable and/or appropriate to the system. These new or modified requirements can be more or less restrictive as they are unique to the specific NIS (including the medicinal product); and

— any substitutions or omissions of requirements, specifications, methods or limits unique to each specific NIS (including the medicinal product), when those provided in this document are not applicable and/or appropriate to the NIS.

The flexibility provided in this document allows it to be applied to many different device and medicinal product combinations. However, it makes it difficult to make a general declaration of conformance to the document. As such, when making any declaration of conformance to this document, specify these deviations, exclusions, substitutions, and omissions supported by adequate justification in the design file.