Needle-free injection systems for medical use - Requirements and test methods (ISO 21649:2023)

EESTI STANDARDI EESSÕNA

NATIONAL FOREWORD

See Eesti standard EVS-EN ISO 21649:2023 sisaldab Euroopa standardi EN ISO 21649:2023 ingliskeelset teksti.	This Estonian standard EVS-EN ISO 21649:2023 consists of the English text of the European standard EN ISO 21649:2023.
Standard on jõustunud sellekohase teate avaldamisega EVS Teatajas.	This standard has been endorsed with a notification published in the official bulletin of the Estonian Centre for Standardisation and Accreditation.
Euroopa standardimisorganisatsioonid on teinud Euroopa standardi rahvuslikele liikmetele kättesaadavaks 08.02.2023.	Date of Availability of the European standard is 08.02.2023.
Standard on kättesaadav Eesti Standardimis-ja Akrediteerimiskeskusest.	The standard is available from the Estonian Centre for Standardisation and Accreditation.

Tagasisidet standardi sisu kohta on võimalik edastada, kasutades EVS-i veebilehel asuvat tagasiside vormi või saates e-kirja meiliaadressile standardiosakond@evs.ee.

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EUROPEAN STANDARD

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English Version

Needle-free injection systems for medical use - Requirements and test methods (ISO 21649:2023)

Systèmes d'injection sans aiguille pour usage médical - Exigences et méthodes d'essai (ISO 21649:2023)

Kanülenlose Injektionsgeräte zur medizinischen Anwendung - Anforderungen und Prüfverfahren (ISO 21649:2023)

This European Standard was approved by CEN on 23 January 2023.

CEN members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for giving this European Standard the status of a national standard without any alteration. Up-to-date lists and bibliographical references concerning such national standards may be obtained on application to the CEN-CENELEC Management Centre or to any CEN member.

This European Standard exists in three official versions (English, French, German). A version in any other language made by translation under the responsibility of a CEN member into its own language and notified to the CEN-CENELEC Management Centre has the same status as the official versions.

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EUROPEAN COMMITTEE FOR STANDARDIZATION
COMITÉ EUROPÉEN DE NORMALISATION
EUROPÄISCHES KOMITEE FÜR NORMUNG

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European foreword

This document (EN ISO 21649:2023) has been prepared by Technical Committee ISO/TC 84 "Devices for administration of medicinal products and catheters" in collaboration with Technical Committee CEN/SS S03 “Syringes” the secretariat of which is held by CCMC.

This European Standard shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by August 2023, and conflicting national standards shall be withdrawn at the latest by August 2023.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. CEN shall not be held responsible for identifying any or all such patent rights.

This document supersedes EN ISO 21649:2009.

Any feedback and questions on this document should be directed to the users’ national standards body/national committee. A complete listing of these bodies can be found on the CEN website.

According to the CEN-CENELEC Internal Regulations, the national standards organizations of the following countries are bound to implement this European Standard: Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Republic of North Macedonia, Romania, Serbia, Slovakia, Slovenia, Spain, Sweden, Switzerland, Türkiye and the United Kingdom.

Endorsement notice

The text of ISO 21649:2023 has been approved by CEN as EN ISO 21649:2023 without any modification.

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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/SS S03, *Syringes,* in accordance with the Agreement on technical cooperation between ISO and CEN (Vienna Agreement).

This second edition cancels and replaces the first edition (ISO 21649:2006), which has been technically revised.

The main changes are as follows:

— changes to update the document to be consistent with the approach and requirements currently in the ISO 11608 series. This includes:

  — use of a risk-based approach to specifications and testing;

  — damp heat testing;

  — water and dust intrusion;

  — transport and lifetime testing.

— changes to address requirements for mass vaccinations such as:

  — requirements to reduce the potential for cross contaminations, such as a requirement for a re-use prevention feature/auto-disable feature for the patient contact portion of a re-usable/ multi-use device;

  — changes to address robustness requirements including long-term repetitive use and for use in harsh environments;

  — inclusion of specific requirement and a test method to address potential transfer of pathogens between patients.

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 specifies the results of the design effort instead of the physical and construction requirements used as the basis for device design, so that innovation in achieving the intended purposes is not unnecessarily restricted.

Standards of this nature intentionally avoid addressing more than the most basic elements regarding the safety and performance of NFISs in humans. Any intended labelling of such devices indicating their use to deliver medicinal products into the body or into specified tissue compartments thereof (e.g. intramuscular, subcutaneous or intradermal), or for the administration of specific pharmaceutical drugs or vaccines, falls under the authority of national governments or supranational agencies regulating the manufacture and marketing of medical devices and pharmaceutical products. Despite certain advantages for intentional interchangeability for dose chambers designed for different NFISs, as well as the potential risks of inadvertent interchangeability, these standards avoid setting forth design specifications for the uniform size, shape and interface of such dose chambers.

The sampling plans for inspection selected for this document are intended to verify the design, at a high confidence level, i.e. the manufacturer's ability to manufacture one “lot” of NFISs, which conforms to the critical product attributes. The sampling plan does not replace the more general manufacturing quality systems, including lot release, which appear in standards on quality systems, e.g. ISO 9001or ISO 13485.

This document assumes 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 according to 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.

Manufacturers are expected to follow a risk-based approach during the design, development, and manufacture of the NFIS. 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 NFIS (including the medicinal product);

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

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

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

1 Scope

This document applies to safety and performance and testing requirements for single-use and multiple-use Needle-Free Injection Systems (NFISs) intended for human use in clinics and other medical settings and for personal use by patients.

The dose chamber of the NFIS is often disposable and intended to be replaced after either a single use or a limited number of uses. It is sometimes separable from the injection mechanism and often termed a "cartridge", "ampoule", "syringe", "capsule" or "disc". In contrast, the dose chamber can also incorporate a permanent internal chamber designed to last through the claimed life of the device, and an additional member or members which eliminate the risk of cross-contamination.

Excluded from this document are drug delivery methods which:

— involve penetration of a part of the device itself into or through skin or mucous membranes (such as needles, tines, micro-needles, implantable slow-release drug devices);

— generate aerosols, droplets, powders or other formulations for inhalation, insufflation, intranasal or oral deposition (such as sprays, inhalers, misters);

— deposit liquids, powders, or other substances on the surface of skin or mucosal surfaces for passive diffusion or ingestion into the body (such as transdermal patches, liquid drops);

— apply sonic or electromagnetic energy (such as ultrasonic or iontophoretic devices);

— infusion systems for adding or metering medication into or through systems of artificial tubes, catheters, and/or needles which themselves enter the body.

2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 7886-3:2020, *Sterile hypodermic syringes for single use — Part 3: Auto-disabled syringes for fixed-dose immunization*

ISO 10993 (all parts), *— Biological evaluation of medical devices*

ISO 11201, *Acoustics — Noise emitted by machinery and equipment — Determination of emission sound pressure levels at a work station and at other specified positions in an essentially free field over a reflecting plane with negligible environmental corrections*

ISO 11202, *Acoustics — Noise emitted by machinery and equipment — Determination of emission sound pressure levels at a work station and at other specified positions applying approximate environmental corrections*

ISO 11204, *Acoustics — Noise emitted by machinery and equipment — Determination of emission sound pressure levels at a work station and at other specified positions applying accurate environmental corrections*

ISO 14155, *Clinical investigation of medical devices for human subjects — Good clinical practice*

ISO 14971:2019, *Medical devices — Application of risk management to medical devices*

IEC 60068-2-27, *Environmental testing — Part 2: Tests. Test Ea and guidance: Shock*

IEC 60068-2-31, *Environmental testing — Part 2-31: Tests. Test Ec: Rough handling shocks, primarily for equipment-type specimens*

IEC 60068-2-64, *Environmental testing — Part 2-64: Tests — Test Fh: Vibration, broad-band random and guidance*

IEC 60529, *Degrees of protection provided by enclosures (IP Code)*

IEC 60721-3-7:1995+AMD1:1996, *Classification of environmental conditions — Part 3-7: Classification of groups of environmental parameters and their severities — Portable and non-stationary use*

IEC 61000-4-2:2008, *Electromagnetic compatibility (EMC) — Part 4-2: Testing and measurement techniques — Electrostatic discharge immunity test*

IEC 61000-4-3:2020, *Electromagnetic compatibility (EMC) — Part 4-3: Testing and measurement techniques — Radiated, radio-frequency, electromagnetic field immunity test*

IEC 61672-1, *Electroacoustics — Sound level meters — Part 1: Specifications*

IEC 62366-1, *Medical devices — Part 1: Application of usability engineering to medical devices*

3 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

ISO and IEC maintain terminology databases for use in standardization at the following addresses:

— ISO Online browsing platform: available at https://www.iso.org/obp

— IEC Electropedia: available at https://www.electropedia.org/

3.1
claimed lifetime
total number of injection strokes that a *needle-free injection system* (3.8), in normal use with recommended user maintenance and before manufacturer overhaul or refurbishment of parts, is expected to administer within its *performance profile* (3.11) specified by the manufacturer

Note 1 to entry: This number may also be expressed as a period of time (e.g. number of days, weeks, months or years) at a corresponding frequency of expected usage (e.g. number of injections per day, week, month or year).

3.2
dose chamber
enclosure that contains and is in direct contact with the pharmaceutical product, and from which the pharmaceutical product is administered to the patient by the needle-free injection system

3.3
dose accuracy
difference between the intended dose and the delivered dose