Nõelata süsteseaded meditsiiniliseks kasutamiseks. Nõuded ja katsemeetodid

Needle-free injectors for medical use - Requirements and test methods

EESTI STANDARDIKESKUS
ESTONIAN CENTRE FOR STANDARDISATION

EESTI STANDARDI EESSÕNA

NATIONAL FOREWORD

Käesolev Eesti standard EVS-EN ISO 21649:2009 sisaldab Euroopa standardi EN ISO 21649:2009 ingliskeelset teksti.	This Estonian standard EVS-EN ISO 21649:2009 consists of the English text of the European standard EN ISO 21649:2009.
Standard on kinnitatud Eesti Standardikeskuse 30.11.2009 käskkirjaga ja jõustub sellekohase teate avaldamisel EVS Teatajas.	This standard is ratified with the order of Estonian Centre for Standardisation dated 30.11.2009 and is endorsed with the notification published in the official bulletin of the Estonian national standardisation organisation.
Euroopa standardimisorganisatsioonide poolt rahvuslikele liikmetele Euroopa standardi teksti kättesaadavaks tegemise kuupäev on 23.09.2009.	Date of Availability of the European standard text 23.09.2009.
Standard on kättesaadav Eesti standardiorganisatsioonist.	The standard is available from Estonian standardisation organisation.

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English Version

Needle-free injectors for medical use - Requirements and test methods (ISO 21649:2006)

Injecteurs sans aiguille à usage médical - Exigences et méthodes d'essai (ISO 21649:2006)

Kanülenlose Injektionsgeräte zur medizinischen Anwendung - Anforderungen und Prüfverfahren (ISO 21649:2006)

This European Standard was approved by CEN on 24 August 2009.

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 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 Management Centre has the same status as the official versions.

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Ref. No. EN ISO 21649:2009: E

Foreword

The text of ISO 21649:2006 has been prepared by Technical Committee ISO/TC 84 “Devices for administration of medicinal products and intravascular catheters” of the International Organization for Standardization (ISO) and has been taken over as EN ISO 21649:2009.

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 March 2010, and conflicting national standards shall be withdrawn at the latest by March 2010.

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

This document supersedes EN ISO 21649:2006.

This document has been prepared under a mandate given to CEN by the European Commission and the European Free Trade Association, and supports essential requirements of EU Directive.

For relationship with EU Directive, see informative Annex ZA, which is an integral part of this document.

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, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland and the United Kingdom.

Endorsement notice

The text of ISO 21649:2006 has been approved by CEN as a EN ISO 21649:2009 without any modification.

Annex ZA
(informative)

Relationship between this European Standard and the Essential Requirements of EU Directive 93/42/EEC on medical devices

This European Standard has been prepared under a mandate given to CEN by the European Commission and the European Free Trade Association to provide a means of conforming to Essential Requirements of the New Approach Directive 93/42/EEC on medical devices.

Once this standard is cited in the Official Journal of the European Union under that Directive and has been implemented as a national standard in at least one Member State, compliance with the clauses of this standard given in table ZA.1 confers, within the limits of the scope of this standard, a presumption of conformity with the corresponding Essential Requirements of that Directive and associated EFTA regulations.

Table ZA.1 — Correspondence between this European Standard and Directive 93/42/EEC on medical devices

Clause(s)/sub-clause(s) of this EN	Essential Requirements (ERs) of Directive 93/42/EEC	Qualifying remarks/Notes
5.1	7.1, 8.1, 8.3, 8.4, 12.7.3, 12.8.1, 12.8.2	
5.3	12.8	
5.4	10, 12.8, 12.9	
5.5	1, 2, 3, 4, 6, 6 a	Ergonomic requirements in ERs 1 are only partly covered in standard by subclauses 5.1 7th paragraph and 5.5.2 Note
5.6.1	4, 9.2, 10.1, 12.8.1	
5.6.2	5	
5.6.3	5	
5.6.4	5	
5.6.5	4, 12.7.1	
5.6.6	4, 12.7.1, 12.7.2	
5.6.7	9.2, 12,5	
6.1, 6.2	1, 3, 4, 5	General conditions for performing tests. Ergonomic requirements in ERs 1 are only partly covered in standard by subclauses 5.1 7th paragraph and 5.5.2 Note
6.2.2	4, 9.2	
6.2.3	5	
6.2.4	5	
6.2.5	5	
6.2.6	4, 9.1, 12.7.1	

Table ZA.1 (continued)

Clause(s)/sub-clause(s) of this EN	Essential Requirements (ERs) of Directive 93/42/EEC	Qualifying remarks/Notes
6.2.7	4, 9.2, 12.7.1	
6.2.8	9.2	
6.3	4, 5	
6.4.1	3, 4, 12.8	
6.4.2	3, 4, 5, 10.2, 12.9, 13.1, 13.2	
7	All applicable ERs	Report on tests
8.1	13.1	
8.2	13.1, 13.3, 13.4, 13.5	Except 13.3 (f) (regarding indication of single-use and consistent across community) and 13.3(a) (regarding representative in the Community)
8.3	13.6	Except 13.6 (h) (regarding if the device bears indication of single use, information on known characteristics and technical factors known to manufacturer that could pose a risk if reused) and 13.6 (q) (regarding date of issue or latest revision of instructions for use)
NOTE	12.1 a	Software requirements are not covered in this standard

WARNING — Other requirements and other EU Directives may be applicable to the product(s) falling within the scope of this standard.

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Introduction

This International Standard applies to needle-free injectors primarily intended to administer medicinal products to humans. Because of the anticipated variation in the designs of such a broad array of devices, this International Standard is promulgated more as a “horizontal” rather than a “vertical” one. Thus, it will tend to specify 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 needle-free injector devices 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, shall fall under the authority of national governments or supranational agencies regulating the manufacture and marketing of medical devices and pharmaceutical products. Such standards are expected to be supplemented by additional requirements and may occasionally be superseded by such regulatory authorities. Despite certain advantages for intentional interchangeability for dose chambers designed for different needle-free injection systems, 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. This issue is left for future initiatives to build upon the standards promulgated herein.

The sampling plans for inspection selected for this International Standard are intended to verify the design, at a high confidence level, i.e., the manufacturer's ability to manufacture one “lot” of needle-free injectors, 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. the ISO 9000 series or ISO 13485.

Needle-free injectors for medical use — Requirements and test methods

1 Scope

This International Standard applies to safety and performance and testing requirements for single-use and multiple-use needle-free injection systems intended for human use in clinics and other medical settings and for personal use by patients.

The dose chamber of the injection system 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 also may be a permanent internal chamber designed to last through the claimed life of the device.

Excluded from this International Standard 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 referenced documents are indispensable for the application 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 3207:1975, *Statistical interpretation of data — Determination of a statistical tolerance interval*

ISO 3746:1995, *Acoustics — Determination of sound power levels of noise sources using sound pressure — Survey method using an enveloping measurement surface over a reflecting plane*

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

ISO 11201:1995, *Acoustics — Noise emitted by machinery and equipment — Measurement of emission sound pressure levels at a work station and at other specified positions — Engineering method in an essentially free field over a reflecting plane*

ISO 11202:1995, *Acoustics — Noise emitted by machinery and equipment — Measurement of emission sound pressure levels at a work station and at other specified positions — Survey method* in situ

ISO 11204:1995, *Acoustics — Noise emitted by machinery and equipment — Measurement of emission sound pressure levels at a work station and at other specified positions — Method requiring environmental corrections*

ISO 14155-1:2003, *Clinical investigation of medical devices for human subjects — Part 1: General requirements*

ISO 14155-2:2003, *Clinical investigation of medical devices for human subjects — Part 2: Clinical investigation plans*

ISO 14253-1:1998, *Geometrical Product Specifications (GPS) — Inspection by measurement of workpieces and measuring equipment — Part 1: Decision rules for proving conformance or non-conformance with specifications*

IEC 60068-2-27:1987, *Environmental testing — Part 2: Tests. Test Ea and guidance: Shock*

IEC 60068-2-30:2005, *Environmental testing — Part 2-30: Tests. Test Db and guidance: Damp heat, cyclic (12 h + 12 h cycle)*

IEC 60068-2-32:1975, *Environmental testing — Part 2: Tests. Test Ed: Free fall*

IEC 60068-2-64:1993, *Environmental testing — Part 2: Test methods — Test Fh: Vibration, broad-band random (digital control) and guidance*

IEC 60601-1-1:2000, *Medical electrical equipment — Part 1-1: General requirements for safety — Collateral standard: Safety requirements for medical electrical systems*

IEC 60721-3-7:2002, *Classification of environmental conditions — Part 3-7: Classification of groups of environmental parameters and their severities — Portable and non-stationary use*

IEC 61000-4-2:2001, *Electromagnetic compatibility (EMC) — Part 4-2: Testing and measurement techniques — Electrostatic discharge immunity test*

IEC 61000-4-3:2002, *Electromagnetic compatibility (EMC) — Part 4-3: Testing and measurement techniques — Radiated, radio-frequency, electromagnetic field immunity test*

IEC 61672-1:2002, *Electroacoustics — Sound level meters — Part 1: Specifications*

GUM:1995, *Guide to the Expression of Uncertainty in Measurement (GUM). BIPM, IEC, IFCC, ISO, IUPAC, IUPAP, OIML* — First edition 1993, corrected and reprinted 1995

3 Terms and definitions

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

3.1
intended dose
amount (volume or mass) of medicinal product intended to be ejected at one time

3.2
ejected dose
amount (volume or mass) of medicinal product ejected at one time

3.3
dose specification
variation of dose quantities (volume or mass) — and a statistical summation of same — which the needle-free injection system will eject for one or for a range of nominal dose quantities, as annunciated by the dose indicator read by typical users of the device