SLOVENSKI STANDARD
SIST EN ISO 21649:2007

01-oktober-2007

Injektorji brez igle za uporabo v medicini - Zahteve in preskusne metode (ISO 21649:2006)

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

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

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

Ta slovenski standard je istoveten z: **EN ISO 21649:2006**

ICS:

11.040.20	Transfuzijska, infuzijska in injekcijska oprema	Transfusion, infusion and injection equipment

SIST EN ISO 21649:2007 **en,fr,de**

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN ISO 21649

June 2006

ICS 11.040.20

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 13 April 2006.

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 Central Secretariat 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 Central Secretariat has the same status as the official versions.

CEN members are the national standards bodies of Austria, Belgium, 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 United Kingdom.

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

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Ref. No. EN ISO 21649:2006: E

Foreword

This document (EN ISO 21649:2006) has been prepared by Technical Committee ISO/TC 84 "Medical devices for injections" in collaboration with CMC.

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 December 2006, and conflicting national standards shall be withdrawn at the latest by December 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(s).

For relationship with EU Directive(s), 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, 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 United Kingdom.

Endorsement notice

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

ANNEX ZA
(informative)

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

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

Once this standard is cited in the Official Journal of the European Communities under that Directive and has been implemented as a national standard in at least one Member State, compliance with the normative 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

Clause(s)/sub-clause(s) of this European Standard	Essential Requirements (ERs) of EU 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	
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
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	
6.2.7	4, 9.2, 12.7.1	

Clause(s)/sub-clause(s) of this European Standard	Essential Requirements (ERs) of EU Directive 93/42/EEC	Qualifying remarks/Notes
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	
8.3	13.6	

WARNING: Other requirements and other EU Directives may be applicable to the products falling within the scope of this European standard.

INTERNATIONAL STANDARD

ISO 21649

First edition
2006-06-01

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

Injecteurs sans aiguille à usage médical — Exigences et méthodes d'essai

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 21649 was prepared by Technical Committee ISO/TC 84, *Devices for administration of medicinal products and intravascular catheters*.

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