SLOVENSKI STANDARD
SIST EN ISO 21649:2010

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Nadomeġļa:
SIST EN ISO 21649:2007

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

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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.

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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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COMITÉ EUROPÉEN DE NORMALISATION
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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of an identical text or by endorsement, at the latest by March 2010, and conflicting national standards shall be withdrawn at the latest by March 2010.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.

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
ISO 21649:2006(E)

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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.