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Nålfria injektorer för medicinskt bruk – Krav och provningsmetoder (ISO 21649:2006)

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

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Europastandarden EN ISO 21649:2009 gäller som svensk standard. Detta dokument innehåller den officiella engelska versionen av EN ISO 21649:2009.

Denna standard ersätter SS-EN ISO 21649:2006, utgåva 1.

The European Standard EN ISO 21649:2009 has the status of a Swedish Standard. This document contains the official English version of EN ISO 21649:2009.

This standard supersedes the Swedish Standard SS-EN ISO 21649:2006, edition 1.

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EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN ISO 21649

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Supersedes EN ISO 21649:2006

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.

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of an identical text or by endorsement, at the latest by March 2010, and conflicting national standards shall be withdrawn at the latest by March 2010.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

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

3.4
dose chamber
final enclosure which holds the pharmaceutical product and has direct contact with it just prior to its administration to the patient

3.5
dose indicator
component of a needle-free injection system showing the intended dose to be delivered

NOTE Depending on the device design, such indication may or may not be apparent before the dose chamber is filled.

3.6
filling device
integral component or components of, or separate or separable accessory(ies) to, a needle-free injector which acts or assists in the transfer of medicinal product between a reservoir and a dose chamber

NOTE Needle-free injection systems in which the dose chamber is or can be pre-filled by the manufacturer of the medicinal product may function without any such filling device. When a filling device is required, it may be as simple as an adapter providing an interface between medicinal reservoir and dose chamber, (e.g., using the piston and plunger of the latter to effect the transfer), or be as complicated as a device with internal channels to actively withdraw and insert the medicinal product from and to the respective containers.

3.7
injection mechanism
components of the needle-free injection system which are designated to harness, store, prevent (as in a “safety” latch), trigger, regulate, control and transfer to the dose chamber and/or its contained medicinal product the energies required for the injection to occur

NOTE This term is not used to refer to separate accessories which transfer energy into the needle-free injector but which are separated from the needle-free injector at the time of the injection (such as a separate spring-cocking mechanism, a gas pressurizing tank, a foot pump or other separate device using electricity, muscle power or other energy source).

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

NOTE 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).

3.9
maximum and minimum dose
volumes, masses or number of units representing the largest and smallest quantities, which the manufacturer designates the needle-free injection system is capable of ejecting by one injection

3.10
reservoir
intermediate enclosure that holds and has contact with the medicinal product immediately prior to its transfer into the dose chamber

NOTE This container is often the vial or other enclosure filled with the medicinal product by the pharmaceutical manufacturer (and termed the “primary packaging” in that industry). It may be single-dose or multi-dose, and usually requires some manipulation by the user, by an accessory filling device, or by the injector device itself to transfer the contents into the dose chamber. There may be no medicinal reservoir for those needle-free injection systems in which the dose chamber is pre-filled by the manufacturer of the medicinal product.