SLOVENSKI STANDARD
kSIST FprEN ISO 20072:2010

01-junij-2010

Inhalatorji za namensko uporabo v medicini - Zahteve in preskusne metode (ISO 20072:2009)

Aerosol drug delivery device design verification - Requirements and test methods (ISO 20072:2009)

Inhalationsgeräte zur gezielten medizinischen Anwendung - Anforderungen und Prüfverfahren (ISO 20072:2009)

Vérification de la conception d'un dispositif d'administration de médicament sous forme d'aérosol - Exigences et méthodes d'essai (ISO 20072:2009)

Ta slovenski standard je istoveten z: **FprEN ISO 20072**

ICS:

11.040.10	Anestezijska, respiratorna in reanimacijska oprema	Anaesthetic, respiratory and reanimation equipment

kSIST FprEN ISO 20072:2010 **en,fr,de**

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

FINAL DRAFT
FprEN ISO 20072

April 2010

ICS 11.040.10

English Version

Aerosol drug delivery device design verification - Requirements and test methods (ISO 20072:2009)

Vérification de la conception d'un dispositif d'administration de médicament sous forme d'aérosol - Exigences et méthodes d'essai (ISO 20072:2009)

Ausführungsverifizierung von Inhalationsgeräten - Anforderungen und Prüfverfahren (ISO 20072:2009)

This draft European Standard is submitted to CEN members for unique acceptance procedure. It has been drawn up by the Technical Committee CEN/TC 205.

If this draft becomes a European Standard, 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.

This draft European Standard was established by CEN 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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EUROPEAN COMMITTEE FOR STANDARDIZATION
COMITÉ EUROPÉEN DE NORMALISATION
EUROPÄISCHES KOMITEE FÜR NORMUNG

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Foreword

The text of ISO 20072:2009 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 FprEN ISO 20072:2010 by Technical Committee CEN/TC 205 “Non-active medical devices” the secretariat of which is held by DIN.

This document is currently submitted to the Unique Acceptance Procedure.

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.

Endorsement notice

The text of ISO 20072:2009 has been approved by CEN as a FprEN ISO 20072:2010 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 and 8 (all parts)	1, 2	Design verification addresses user interface, labelling, general design requirements, environmental and mechanical testing
5 (all parts) and 6.4	3	
5.6.2	4	
5.6.2 through 5.6.7	5	
5.2	6	Essential requirement 6.a relating to the clinical evaluation is not specifically addressed in the present standard.
5.1, parts h, i, j, l and 5.2	7	
5.1, parts h, i, j, l and 5.2	8	
5.1 part d and 5.6	9	
5.1, 5.5, 6.4.2, 6.4.3, 6.4.4, 8.2	10	
5.1, part k, m, n and 5.6.8	12	
8 (all parts)	13	The parts of ER 13.3.a) relating to the address of manufacturer and to the authorized representative are not addressed. ERs 13.3.f) and 13.6.h) relating to single-use are not addressed. ER 13.6.q) is not addressed.

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

INTERNATIONAL STANDARD

ISO 20072

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Aerosol drug delivery device design verification — Requirements and test methods

Vérification de la conception d'un dispositif d'administration de médicament sous forme d'aérosol — Exigences et méthodes d'essai

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