



SLOVENSKI STANDARD SIST EN ISO 20072:2013

01-maj-2013

Nadomešča:
SIST EN ISO 20072:2011

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)

Ausführungsverifizierung von Inhalationsgeräten - 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: EN ISO 20072:2013

ICS:

11.040.10	Anestezijska, respiratorna in reanimacijska oprema	Anaesthetic, respiratory and reanimation equipment
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NORME EUROPÉENNE
EUROPÄISCHE NORM

EN ISO 20072

February 2013

ICS 11.040.10

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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 European Standard was approved by CEN on 8 January 2013.

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-CENELEC 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-CENELEC Management Centre has the same status as the official versions.

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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 EN ISO 20072:2013 by Technical Committee CEN/TC 205 “Non-active medical devices” the secretariat of which is held by DIN.

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 August 2013, and conflicting national standards shall be withdrawn at the latest by August 2013.

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 20072:2010.

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

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Endorsement notice

The text of ISO 20072:2009 has been approved by CEN as EN ISO 20072:2013 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)/subclause(s) of this EN	Essential Requirements (ERs) of Directive 93/42/EEC	Qualifying remarks/Notes
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, parts k, m, n and 5.6.8	12	
8 (all parts)	13	<p>The parts of ER 13.3 a) relating to the address of manufacturer and to the authorized representative are not addressed.</p> <p>ERs 13.3 f) and 13.6 h) relating to single-use are not addressed.</p> <p>ER 13.6 q) is not addressed.</p>

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

First edition
2009-08-01

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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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 20072 was prepared by Technical Committee ISO/TC 84, *Devices for administration of medicinal products and intravascular catheters*.

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Introduction

This International Standard applies to hand-held aerosol drug delivery devices (ADDD) intended to administer medication to humans. To avoid unnecessarily restricting innovation, given the broad variation in device designs, this International Standard addresses the more general design/labelling requirements rather than specific physical and prescriptive design requirements. However, this International Standard does require the elaboration of a device functionality profile (DFP) specific to the ADDD in question. This International Standard also addresses ADDD design requirements from both the user interface and safety perspectives.

An ADDD is used as part of a system consisting of the ADDD, the container, the medication and the labelling, including the instructions for use. Therefore, design verification of the ADDD includes a final system verification test conducted in accordance with the instructions for use.

From a regulatory perspective, the ADDD system may be reviewed and approved as part of a drug product (combination of ADDD and medication) or as a device by itself. For the purposes of this International Standard, such regulatory distinctions do not alter the intent of the design verification process described herein. As an example, in the European Union (EU), if an ADDD is placed on the market in such a way that the ADDD and the medication form a single integral product (i.e. the system) that is intended exclusively for use in the given combination and which is not refillable, that single product shall be governed by Directive 2001/83/EEC. However, the relevant essential requirements of Annex I of the Medical Device Directive (93/42/EEC) shall apply as far as safety and performance-related ADDD features are concerned, which is the specific objective of this design verification standard.

Regardless of the distinctions ("drug" or "device," pre-filled or refillable), it is recognised that ADDD design verification is an important component of the overall validation process. Moreover, design verification is iterative, to be conducted at various phases throughout the ADDD's development and subsequent ADDD post-approval modifications. In all instances, design verification is conducted using the phase-appropriate instructions for use. It is understood that in the early phases of ADDD development an appropriate subset of the requirements contained herein might apply, but that all of the requirements will be satisfied as part of the final design verification exercise. Furthermore, design verification should be considered a minimum requirement for the safe and effective use of the ADDD, and in many instances additional testing may be appropriate as indicated by a risk assessment that shall also be conducted.

This International Standard introduces the requirement for developers and/or manufacturers to create a device functionality profile (DFP) for a given ADDD based on the ISO Standard for device risk assessment (as a part of ISO 14971). The device functionality profile defines the parameters and tolerance intervals used to verify the ADDD's ability to meet the manufacturer's design specifications during in-use conditions and following environmental and electromechanical extreme use conditions. This International Standard also includes a system verification test conducted at standard atmosphere and nominal flow rate as a simple bridge between the device design and the patient interface.

The purpose of this International Standard is to ensure a method and guide for independent testing of the repeatability and reproducibility of ADDD functionality that verifies compliance with its design specification. The design verification process may include use of applicable regulatory agency requirements and/or test methods. The sampling plans for this International Standard are intended to verify the design at a high confidence level. They do 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).

Figure 1 illustrates the process this International Standard advises to use in order to assess and verify whether a design meets the determined DFP.

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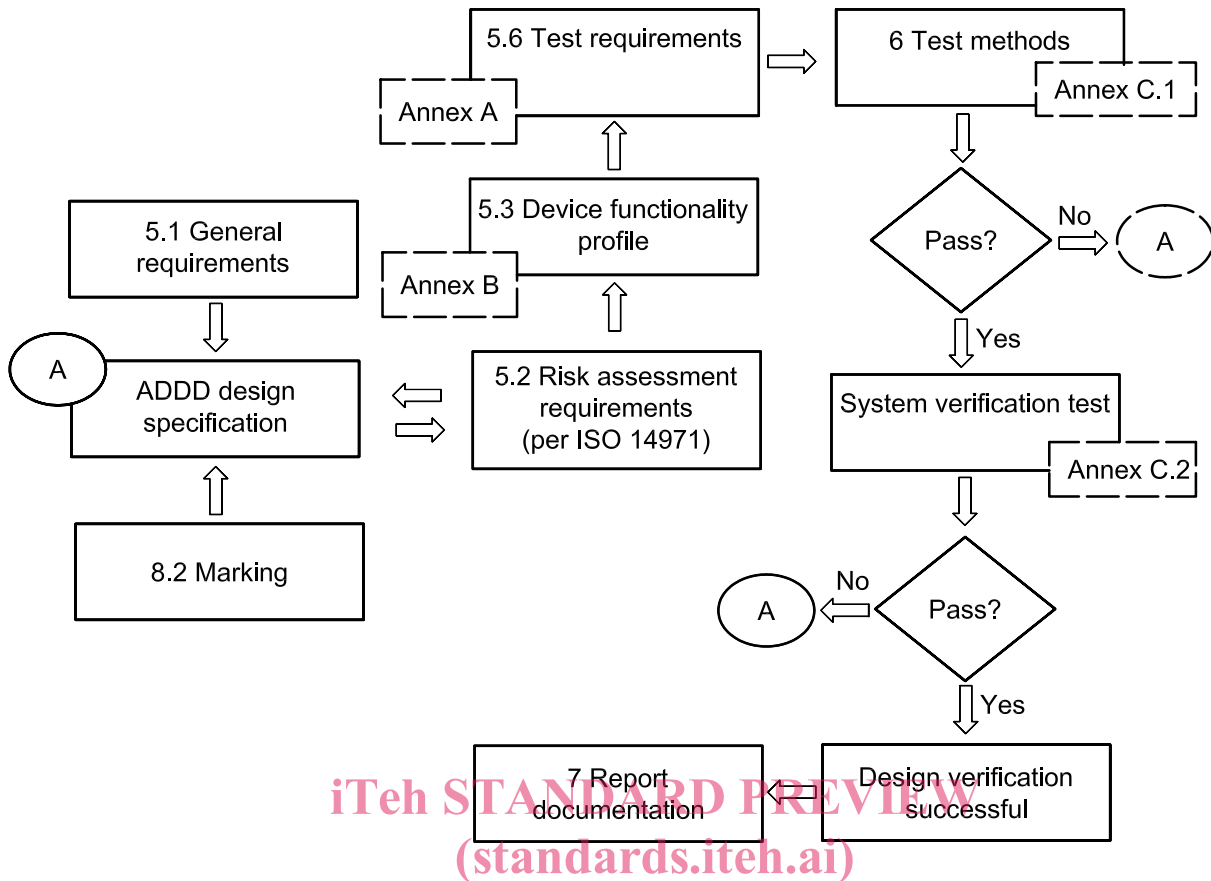


Figure 1 — ADDD design verification process

This International Standard specifically addresses the most basic elements regarding the safe and effective use of ADDD in humans. It does not define the pharmaceutical or clinical performance of an ADDD. Any labelling indicating ADDD use to deliver medication to specific regions of the respiratory tract falls under the authority of national governments or regional agencies regulating the manufacture and marketing of medical devices and pharmaceutical products. In some countries national regulations exist, and their requirements can supersede or complement this International Standard.

For a given manufacturer, existing marketed products and those currently under development might not fulfil some of the requirements. However, manufacturers should comply with this International Standard when improving the functional design of existing ADDDs or developing new ADDDs to obtain an even higher level of quality.

Annex A describes the reasoning for establishing the various requirements in this International Standard.

Aerosol drug delivery device design verification — Requirements and test methods

1 Scope

This International Standard applies to the design, labelling, instructions for use and testing requirements for hand-held single- and multi-use aerosol drug delivery devices (ADDDs) intended to deliver a metered or pre-metered aerosolized medication to or by means of the human respiratory tract (including nasal, oral, tracheal, bronchial and alveolar sites). This International Standard applies to both refillable and disposable devices intended for personal use.

This International Standard is intended for device design verification and not for drug product quality assessment. The objective of this International Standard is to verify, by laboratory (*in-vitro*) testing, that the ADDD design consistently meets the manufacturer's design specification by satisfying a device functionality profile and system verification test both of which are determined from a risk assessment and evaluated in accordance with the instructions for use.

This International Standard excludes continuous or semi-continuous aerosolization devices covered in ISO 27427, aerosolization devices which do not emit active pharmaceutical ingredient (API), general purpose aerosolization devices (for use with ventilators) and atomizers.

This International Standard does not apply to manufacturers of single parts or components of the ADDDs [e.g. (spray) pumps, valves, containers, etc.].

NOTE There might be times when a device falls under the scope of this International Standard and that of ISO 27427. The committee envisions that the intended use of the product and the risk assessment of the device will derive which International Standard the manufacturer chooses for design verification of the ADDD. This International Standard outlines the process by which ADDD design verification is to be performed in conjunction with a risk-based device functionality profile of the ADDD with either the medication, a placebo or a representative medication. ISO 27427 outlines the process by which the characterization of the aerodynamic aerosol performance of a nebulizing system for use with a non-specific class of active pharmaceutical ingredient(s) is made.

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 14971:2007, *Medical devices — Application of risk management to medical devices*

ISO 10993-1, *Biological evaluation of medical devices — Part 1: Evaluation and testing*

ISO 11135-1, *Sterilization of health care products — Ethylene oxide — Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices*

ISO 11137 (all parts), *Sterilization of health care products — Radiation*

ISO 15223-1, *Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied — Part 1: General requirements*

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ISO 17665-1, *Sterilization of health care products — Moist heat — Part 1: Requirements for the development, validation and routine control of a sterilization process for medical devices*

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

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

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

IEC 60068-2-64, *Environmental testing — Part 2-64: Tests — Test Fh: Vibration, broadband random and guidance*

IEC 60601-1, *Medical electrical equipment — Part 1: General requirements for basic safety and essential performance*

IEC 60601-1-2, *Medical electrical equipment — Part 1-2: General requirements for basic safety and essential performance — Collateral standard: Electromagnetic compatibility — Requirements and tests*

IEC 60601-1-8, *Medical electrical equipment — Part 1-8: General requirements for basic safety and essential performance — Collateral standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems*

IEC 60721-3-7, *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, *Electromagnetic compatibility (EMC) — Part 4-2: Testing and measurement techniques — Electrostatic discharge immunity test*

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

IEC 62304, *Medical device software — Software life-cycle processes*

IEC 62366, *Medical devices — Application of usability engineering to medical devices*

3 Terms and definitions

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

3.1
accessory
add-on device (specifically referenced in the ADDD instructions for use) that may be used in conjunction with an ADDD to enable or enhance its performance

EXAMPLE Spacers, holding chambers, actuation counters, content indicators, etc.

3.2
active pharmaceutical ingredient
API
molecule(s) responsible for producing the intended therapeutic action

3.3
actuation
operation of the ADDD to release medication that will be aerosolized

NOTE The actuation can consist of the loading and release of the medication or only the release of the medication.

3.4**actuation counter
dose counter**

mechanism numerically counting down the number of actuations

NOTE The actuation counter may either be an accessory or integrated with the ADDD.

3.5**ADD system**

integrated system comprised of the ADDD, patient interface and the medication (i.e. a combination product)

3.6**aerosol**

suspension of particles in gas

[ISO 27427:2009, definition 3.1]

NOTE 1 Particles can be liquid and/or solid.

NOTE 2 The gas can be the driving gas or ambient air.

3.7**aerosol drug delivery device****ADD**

device for the delivery of medication in the form of an aerosol

3.8**claimed lifetime**

time period, and/or number of actuations, stated by the ADDD manufacturer within which the device functionality profile of the ADDD will remain within the design specification comprising the timeframe within which the patient uses the ADDD

NOTE Claimed lifetime is not necessarily the same as the shelf life of the ADDD.

3.9**claimed lifetime testing**

performance evaluation simulating the claimed lifetime stated by the ADDD manufacturer within which the device functionality profile of the ADDD will remain within the design specification

3.10**combination product**

ADD used with a specific medication

3.11**content indicator**

visual indicator showing the amount of medication remaining in the ADDD

NOTE A content indicator can be either an accessory or integrated with the ADDD.

3.12**design verification**

confirmation by examination and provision of objective evidence that specified design requirements have been fulfilled

3.13**device functionality profile****DFP**

parameters and tolerance intervals used to assess whether the ADDD meets the manufacturer's design specification

NOTE It must be possible to evaluate the properties using laboratory (*in vitro*) testing.