ICS 11.100.10 SLOVENSKÁ TECHNICKÁ NORMA November 2015

STN	**Diagnostické zdravotnícke pomôcky in vitro. Skúšanie stability diagnostických činidiel in vitro (ISO 23640: 2011).**	**STN EN ISO 23640** 85 1014

In vitro diagnostic medical devices - Evaluation of stability of in vitro diagnostic reagents (ISO 23640:2011)

Táto norma obsahuje anglickú verziu európskej normy.
This standard includes the English version of the European Standard.

Táto norma bola oznámená vo Vestníku ÚNMS SR č. 10/15

Obsahuje: EN ISO 23640:2015, ISO 23640:2011

Oznámením tejto normy sa ruší
STN EN ISO 23640 (85 1014) z júna 2013

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN ISO 23640

June 2015

ICS 11.100.10

Supersedes EN ISO 23640:2013

English Version

In vitro diagnostic medical devices - Evaluation of stability of in vitro diagnostic reagents (ISO 23640:2011)

Dispositifs médicaux de diagnostic in vitro - Évaluation de la stabilité des réactifs de diagnostic in vitro (ISO 23640:2011)

In-vitro-Diagnostika - Haltbarkeitsprüfung von Reagenzien für in-vitro-diagnostische Untersuchungen (ISO 23640:2011)

This European Standard was approved by CEN on 3 June 2015.

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

CEN-CENELEC Management Centre: Avenue Marnix 17, B-1000 Brussels

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Foreword

The text of ISO 23640:2011 has been prepared by Technical Committee ISO/TC 212 “Clinical laboratory testing and in vitro diagnostic test systems” of the International Organization for Standardization (ISO) and has been taken over as EN ISO 23640:2015 by Technical Committee CEN/TC 140 “In vitro diagnostic 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of an identical text or by endorsement, at the latest by December 2015, and conflicting national standards shall be withdrawn at the latest by June 2018.

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 23640:2013.

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.

The following referenced documents are indispensable for the application of this document. For undated references, the edition of the referenced document (including any amendments) listed below applies. For dated references, only the edition cited applies. However, for any use of this standard ‘within the meaning of Annex ZA’, the user should always check that any referenced document has not been superseded and that its relevant contents can still be considered the generally acknowledged state-of-art.

When an IEC or ISO standard is referred to in the ISO standard text, this shall be understood as a normative reference to the corresponding EN standard, if available, and otherwise to the dated version of the ISO or IEC standard, as listed below.

NOTE The way in which these referenced documents are cited in normative requirements determines the extent (in whole or in part) to which they apply.

Table — Correlation between normative references and dated EN and ISO standards

Normative references as listed in Clause 2 of the ISO standard	Equivalent dated standard	
	EN	ISO
ISO 14971	EN ISO 14971:2012	ISO 14971:2007, Corrected version 2007-10-01

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.

Endorsement notice

The text of ISO 23640:2011 has been approved by CEN as EN ISO 23640:2015 without any modification.

Annex ZA
(informative)

Relationship between this European Standard and the Essential Requirements of EU Directive 98/79/EC

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 Directive 98/79/EC *in vitro* diagnostic 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 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.

NOTE 1 Where a reference from a clause of this standard to the risk management process is made, the risk management process needs to be in compliance with Directive 98/79/EC. This means that risks have to be reduced 'as far as possible', 'to a minimum', 'to the lowest possible level', 'minimized' or 'removed', according to the wording of the corresponding essential requirement.

NOTE 2 The manufacturer's policy for determining acceptable risk must be in compliance with essential requirements Part A: 1, 2 and 5; Part B: 1.2, 2, 3, 5, 6 and 7 of the Directive.

NOTE 3 This Annex ZA is based on normative references according to the table of references in the European foreword, replacing the references in the core text.

NOTE 4 When an Essential Requirement does not appear in Table ZA.1, it means that it is not addressed by this European Standard.

Table ZA.1 — Correspondence between this European Standard and Directive 98/79/EC

Clause(s)/sub-clause(s) of this EN	Essential Requirements (ERs) of Directive 98/79/EC	Qualifying remarks/notes
4.1, 4.2, 4.3, 5.1, 5.2, 5.3	A.4	This Standard covers stability evaluations of diverse transport, storage and use conditions that are foreseen by the IVD manufacturer based on the intended purpose and the anticipated use of the device. In case of self-testing devices, the tested conditions should reflect the normal routine conditions of use by a lay-user. Particular storage, transport and/or handling conditions must be specified by the IVD manufacturer as provided on the label and in the instructions for use.

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

INTERNATIONAL STANDARD

ISO 23640

First edition
2011-12-01

In vitro diagnostic medical devices — Evaluation of stability of *in vitro* diagnostic reagents

Dispositifs médicaux de diagnostic in vitro — Évaluation de la stabilité des réactifs de diagnostic in vitro

Reference number
ISO 23640:2011(E)

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ISO copyright office
Case postale 56 • CH-1211 Geneva 20
Tel. + 41 22 749 01 11
Fax + 41 22 749 09 47
E-mail copyright@iso.org
Web www.iso.org

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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 23640 was prepared by Technical Committee ISO/TC 212, *Clinical laboratory testing and* in vitro *diagnostic test systems*.

Introduction

One important aspect of the development and manufacture of *in vitro* diagnostic (IVD) medical device reagents is initially designing the stability of a product, then determining and verifying the expiry date of the product that is placed on the market. To determine shelf life, transport stability, and in-use stability, the manufacturer performs an evaluation. In order to provide this important information to the customer, the manufacturer identifies critical factors that might influence stability of the IVD reagent and carefully evaluates these characteristics. Stability of the IVD reagent affects the performance of the device and therefore has an impact on patient results.

It is the manufacturer's responsibility to determine and monitor stability of IVD reagents to ensure that performance characteristics of the product are maintained. This is best accomplished by developing a stability evaluation protocol, and producing valid data and analysis to establish appropriate shelf life, transport limitations and in-use stability information, which are then provided to the customers.

The basis for this ISO standard is EN 13640, *Stability testing of* in vitro *diagnostic reagents*[2].

INTERNATIONAL STANDARD ISO 23640:2011(E)

In vitro diagnostic medical devices — Evaluation of stability of *in vitro* diagnostic reagents

1 Scope

This International Standard is applicable to the stability evaluation of *in vitro* diagnostic medical devices, including reagents, calibrators, control materials, diluents, buffers and reagent kits, hereinafter called IVD reagents. This International Standard can also be applied to specimen collection devices that contain substances used to preserve samples or to initiate reactions for further processing of the sample in the collection device.

This International Standard specifies general requirements for stability evaluation and gives specific requirements for real time and accelerated stability evaluation when generating data in:

— the establishment of IVD reagent shelf life, including transport conditions suitable to ensure that product specifications are maintained;

— the establishment of stability of the IVD reagent in use after the first opening of the primary container;

EXAMPLE On-board stability, stability after reconstitution, open vial/bottle stability.

— the monitoring of stability of IVD reagents already placed on the market;

— the verification of stability specifications after modifications of the IVD reagent that might affect stability.

This International Standard is not applicable to instruments, apparatus, equipment, systems or specimen receptacles, or the sample subject to examination.

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, *Medical devices — Application of risk management to medical devices*