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BS EN ISO 23640:2015



BSI Standards Publication

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

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This British Standard is the UK implementation of EN ISO 23640:2015. It is identical to ISO 23640:2011. It supersedes BS EN ISO 23640:2013 which is withdrawn.

The UK participation in its preparation was entrusted to Technical Committee CH/212, IVDs.

A list of organizations represented on this committee can be obtained on request to its secretary.

This publication does not purport to include all the necessary provisions of a contract. Users are responsible for its correct application.

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Amendments/corrigenda issued since publication

Date	Text affected
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EUROPÄISCHE NORM

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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.

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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EUROPEAN COMMITTEE FOR STANDARDIZATION
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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.

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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	<p>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.</p> <p>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.</p>

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