BS EN ISO 23640:2013

BSI Standards Publication

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

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 It supersedes BS EN ISO 23640:2011 which is withdrawn.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

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Compliance with a British Standard cannot confer immunity from legal obligations.

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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 8 January 2013.

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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 23640:2013 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of an identical text or by endorsement, at the latest by August 2013, and conflicting national standards shall be withdrawn at the latest by August 2013.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 23640:2011.

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.

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Endorsement notice

The text of ISO 23640:2011 has been approved by CEN as EN ISO 23640:2013 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 one means of conforming to Essential Requirements of the New Approach Directive 98/79/EC on *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.

Table ZA.1 — Correspondence between this European Standard and Directive 98/79/EC on *in vitro* diagnostic medical devices

Clauses/subclauses of this European Standard	Essential Requirements of the Directive 98/79/EC	Qualifying remarks/Notes
4.1, 4.2, 4.3, 5.1, 5.2, 5.3	A.4	

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