SLOVENSKI STANDARD
oSIST prEN ISO 23640:2026

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In vitro diagnostične medicinske naprave - Vrednotenje stabilnosti in vitro diagnostičnih reagentov (ISO/DIS 23640:2026)

In vitro diagnostic medical devices - Evaluation of stability of in vitro diagnostic reagents (ISO/DIS 23640:2026)

In-vitro-Diagnostika - Haltbarkeitsprüfung von Reagenzien für in-vitro-diagnostische Untersuchungen (ISO/DIS 23640:2026)

Dispositifs médicaux de diagnostic in vitro - Évaluation de la stabilité des réactifs de diagnostic in vitro (ISO/DIS 23640:2026)

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11.100.10	Diagnostični preskusni sistemi in vitro	In vitro diagnostic test systems

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ISO/DIS 23640

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

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Foreword

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This document was prepared by Technical Committee ISO/TC 212 *Medical laboratories and in vitro diagnostic systems.*

This second edition cancels and replaces the first edition (ISO 23640:2011), which has been technically revised.

The main changes are as follows:

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Any feedback or questions on this document should be directed to the user's national standards body. A complete listing of these bodies can be found at www.iso.org/members.html.

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].

NOTE Regulatory approval requirements may vary, check with Regulatory Authorities in the target market.