



SLOVENSKI STANDARD

oSIST prEN ISO 22367:2025

01-junij-2025

Medicinski laboratoriji - Uporaba obvladovanja tveganja v medicinskih laboratorijih (ISO/DIS 22367:2025)

Medical laboratories - Application of risk management to medical laboratories (ISO/DIS 22367:2025)

Medizinische Laboratorien - Anwendung des Risikomanagements auf medizinische Laboratorien (ISO/DIS 22367:2025)

Laboratoires de biologie médicale - Application de la gestion des risques aux laboratoires de biologie médicale (ISO/DIS 22367:2025)

Ta slovenski standard je istoveten z: prEN ISO 22367

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ICS:

03.100.01	Organizacija in vodenje podjetja na splošno	Company organization and management in general
11.100.01	Laboratorijska medicina na splošno	Laboratory medicine in general

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en,fr,de



DRAFT International Standard

ISO/DIS 22367

Medical laboratories — Application of risk management to medical laboratories

*Laboratoires de biologie médicale — Application de la gestion
des risques aux laboratoires de biologie médicale*

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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 (ISO 22367:2020), which has been technically revised. The main changes compared to the previous edition are as follows:

- The application of risk management to processes has been emphasized;
- Reactive and proactive risk management has been discussed, differentiated, and illustrated;
- The content is as far as possible in agreement the requirements for risk management in ISO 15189:2022;
- The relation with ISO 15189:2022 is indicated in [Annex A](#) in which [Figure A.1](#) provides a flow chart for the underlying quality management system to underpin this standard;
- Annex [I.5](#) has been slightly modified to emphasize that risks most often require benefit-risk assessment to determine risk acceptability.

Recognizing the effort required for translation, only [Annex A](#) and [Annex I](#) as mentioned above and Annex [sections F.1, F.6.1 and F.8](#) have been modified. The remaining annexes have been retained unchanged after review from the prior edition.

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