ILNAS

Institut luxembourgeois de la normalisation
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des produits et services

# ILNAS-EN ISO 15189:2022

## Medical laboratories - Requirements for quality and competence (ISO 15189:2022)

Laboratoires de biologie médicale - Exigences concernant la qualité et la compétence (ISO 15189:2022)

Medizinische Laboratorien - Anforderungen an die Qualität und Kompetenz (ISO 15189:2022)

12/2022

**National Foreword**

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# EUROPEAN STANDARD
# NORME EUROPÉENNE
# EUROPÄISCHE NORM

**EN ISO 15189**

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Supersedes EN ISO 15189:2012, EN ISO 22870:2016

English Version

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**CEN-CENELEC Management Centre: Rue de la Science 23, B-1040 Brussels**



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## European foreword

This document (EN ISO 15189:2022) has been prepared by Technical Committee ISO/TC 212 "Clinical laboratory testing and in vitro diagnostic test systems" in collaboration with 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of an identical text or by endorsement, at the latest by June 2023, and conflicting national standards shall be withdrawn at the latest by December 2025.

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INTERNATIONAL STANDARD

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# Medical laboratories — Requirements for quality and competence

*Laboratoires de biologie médicale — Exigences concernant la qualité et la compétence*



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