



Institut luxembourgeois de la normalisation
de l'accréditation, de la sécurité et qualité
des produits et services

ILNAS-EN ISO 15189:2007

Medical laboratories - Particular requirements for quality and competence (ISO 15189:2007)

Laboratoires d'analyses de biologie
médicale - Exigences particulières
concernant la qualité et la compétence
(ISO 15189:2007)

Medizinische Laboratorien - Besondere
Anforderungen an die Qualität und
Kompetenz (ISO 15189:2007)

04/2007



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ILNAS-EN ISO 15189:2007

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Medical laboratories - Particular requirements for quality and competence (ISO 15189:2007)

Laboratoires d'analyses de biologie médicale - Exigences particulières concernant la qualité et la compétence (ISO 15189:2007)

Medizinische Laboratorien - Besondere Anforderungen an die Qualität und Kompetenz (ISO 15189:2007)

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Foreword

This document (EN ISO 15189:2007) 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of an identical text or by endorsement, at the latest by October 2007, and conflicting national standards shall be withdrawn at the latest by October 2007.

This document supersedes EN ISO 15189:2003.

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The text of ISO 15189:2007 has been approved by CEN as EN ISO 15189:2007 without any modifications.

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Medical laboratories — Particular requirements for quality and competence

*Laboratoires d'analyses de biologie médicale — Exigences particulières
concernant la qualité et la compétence*



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Foreword

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ISO 15189 was prepared by Technical Committee ISO/TC 212, *Clinical laboratory testing and in vitro diagnostic test systems*.

This second edition cancels and replaces the first edition (ISO 15189:2003) which has been technically revised in order to align it more closely with the second edition of ISO/IEC 17025.