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ILNAS

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

ILNAS-EN ISO 15189:2003

Medical laboratories - Particular requirements for quality and competence (ISO 15189:2003)

Medizinische Laboratorien - Besondere Anforderungen an die Qualität und Kompetenz (ISO 15189:2003)

Laboratoires d'analyses de biologie médicale - Exigences particulières concernant la qualité et la compétence (ISO 15189:2003)

02/2003

National Foreword

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EUROPEAN STANDARD
NORME EUROPÉENNE
EUROPÄISCHE NORM

EN ISO 15189

February 2003

ICS 11.100

English version

Medical laboratories - Particular requirements for quality and competence (ISO 15189:2003)

Laboratoires d'analyses de biologie médicale - Exigences particulières concernant la qualité et la compétence (ISO 15189:2003)

Medizinische Laboratorien - Besondere Anforderungen an die Qualität und Kompetenz (ISO 15189:2003)

This European Standard was approved by CEN on 17 January 2003.

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COMITÉ EUROPÉEN DE NORMALISATION
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Foreword

This document (EN ISO 15189:2003) 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of an identical text or by endorsement, at the latest by August 2003, and conflicting national standards shall be withdrawn at the latest by August 2003.

According to the CEN/CENELEC Internal Regulations, the national standards organizations of the following countries are bound to implement this European Standard: Austria, Belgium, Czech Republic, Denmark, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Luxembourg, Malta, Netherlands, Norway, Portugal, Slovakia, Spain, Sweden, Switzerland and the United Kingdom.

Endorsement notice

The text of ISO 15189:2003 has been approved by CEN as EN ISO 15189:2003 without any modifications.

NOTE Normative references to International Standards are listed in Annex ZA (normative).

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Annex ZA
(normative)

Normative references to international publications with their relevant European publications

This European Standard incorporates by dated or undated reference, provisions from other publications. These normative references are cited at the appropriate places in the text and the publications are listed hereafter. For dated references, subsequent amendments to or revisions of any of these publications apply to this European Standard only when incorporated in it by amendment or revision. For undated references the latest edition of the publication referred to applies (including amendments).

NOTE Where an International Publication has been modified by common modifications, indicated by (mod.), the relevant EN/HD applies.

Publication	Year	Title	EN	Year
ISO 9000	2000	Quality management systems - Fundamentals and vocabulary	EN ISO 9000	2000
ISO 9001	2000	Quality management systems - Requirements	EN ISO 9001	2000
ISO/IEC 17025	1999	General requirements for the competence of testing and calibration laboratories	EN ISO/IEC 17025	2000

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