

# ILNAS

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

**ILNAS-EN 13532:2002**



## National Foreword

This European Standard EN 13532:2002 was adopted as Luxembourgish Standard ILNAS-EN 13532:2002.

Every interested party, which is member of an organization based in Luxembourg, can participate for FREE in the development of Luxembourgish (ILNAS), European (CEN, CENELEC) and International (ISO, IEC) standards:

- Participate in the design of standards
- Foresee future developments
- Participate in technical committee meetings

<https://portail-qualite.public.lu/fr/normes-normalisation/participer-normalisation.html>

### **THIS PUBLICATION IS COPYRIGHT PROTECTED**

Nothing from this publication may be reproduced or utilized in any form or by any mean - electronic, mechanical, photocopying or any other data carries without prior permission!

EUROPEAN STANDARD <sup>ILNAS-EN 13532:2002</sup> **EN 13532**  
NORME EUROPÉENNE  
EUROPÄISCHE NORM

April 2002

ICS 11.100

English version

**General requirements for in vitro diagnostic medical devices for  
self-testing**

Exigences générales relatives aux dispositifs médicaux de  
diagnostic in vitro destinés à des auto-diagnostics

Allgemeine Anforderungen an In-vitro-Diagnostika zur  
Eigenanwendung

This European Standard was approved by CEN on 27 December 2001.

CEN members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for giving this European Standard the status of a national standard without any alteration. Up-to-date lists and bibliographical references concerning such national standards may be obtained on application to the Management Centre or to any CEN member.

This European Standard exists in three official versions (English, French, German). A version in any other language made by translation under the responsibility of a CEN member into its own language and notified to the Management Centre has the same status as the official versions.

CEN members are the national standards bodies of Austria, Belgium, Czech Republic, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Luxembourg, Malta, Netherlands, Norway, Portugal, Spain, Sweden, Switzerland and United Kingdom.



EUROPEAN COMMITTEE FOR STANDARDIZATION  
COMITÉ EUROPÉEN DE NORMALISATION  
EUROPÄISCHES KOMITEE FÜR NORMUNG

**Management Centre: rue de Stassart, 36 B-1050 Brussels**