

# **In vitro diagnostic medical devices — Measurement of quantities in biological samples — Metrological traceability of values for catalytic concentration of enzymes assigned to calibrators and control materials**

The European Standard EN ISO 18153:2003 has the status of a  
British Standard

ICS 07.100.10

## National foreword

This British Standard is the official English language version of EN ISO 18153:2003. It is identical with ISO 18153:2003.

The UK participation in its preparation was entrusted to Technical Committee CH/212, In vitro diagnostics, which has the responsibility to:

- aid enquirers to understand the text;
- present to the responsible international/European committee any enquiries on the interpretation, or proposals for change, and keep the UK interests informed;
- monitor related international and European developments and promulgate them in the UK.

A list of organizations represented on this committee can be obtained on request to its secretary.

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### Summary of pages

This document comprises a front cover, an inside front cover, the EN title page, pages 2 to 16, an inside back cover and a back cover.

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### Amendments issued since publication

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English version

In vitro diagnostic medical devices - Measurement of quantities  
in biological samples - Metrological traceability of values for  
catalytic concentration of enzymes assigned to calibrators and  
control materials (ISO 18153:2003)

Dispositifs médicaux de diagnostic in vitro - Mesurage des  
grandeurs dans des échantillons d'origine biologique -  
Traçabilité métrologique des valeurs de concentration  
catalytique des enzymes attribuées aux agents  
d'étalonnage et aux matériaux de contrôle (ISO  
18153:2003)

In-vitro-Diagnostika - Messung von Größen in Proben  
biologischen Ursprungs - Metrologische Rückführbarkeit  
von Werten der katalytischen Konzentration von Enzymen,  
die Kalibratoren und Kontrollmaterialien zugeordnet sind  
(ISO 18153: 2003)

This European Standard was approved by CEN on 11 March 2003.

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