

**In vitro diagnostic  
medical devices —  
Measurement of  
quantities in samples of  
biological origin —  
Presentation of  
reference measurement  
procedures**

The European Standard EN 12286:1998, with the incorporation of amendment A1:2000 has the status of a British Standard

ICS 11.100

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## National foreword

This British Standard is the English language version of EN 12286:1998, including amendment A1:2000.

The UK participation in its preparation was entrusted to Technical Committee CH/69, In vitro diagnostic systems, which has the responsibility to:

- aid enquirers to understand the text;
- present to the responsible 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 14, an inside back cover and a back cover.

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### Amendments issued since publication

Amd. No.	Date	Text affected
11034	January 2001	Addition of informative annex ZA

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Descriptors: medicine, bioassay, in vitro diagnostics, sampling, measurements, procedure

English version

## In vitro diagnostic medical devices — Measurement of quantities in samples of biological origin — Presentation of reference measurement procedures

(includes amendment A1:2000)

Dispositifs médicaux de diagnostic in vitro —  
Mesure des grandeurs dans des échantillons  
d'origine biologique — Présentation des modes  
opératoires de mesure de référence  
(inclut l'amendement A1:2000)

In-Vitro-Diagnostika — Messung von Größen in  
Proben biologischen Ursprungs — Darstellung von  
Referenzmeßverfahren  
(enthält Änderung A1:2000)

This European Standard was approved by CEN on 14 October 1998. Amendment A1 was approved by CEN on 9 April 2000.

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