



National Standards Authority of Ireland

IRISH STANDARD

I.S. EN 12286:1999

ICS 11.100

**IN VITRO DIAGNOSTIC MEDICAL DEVICES -
MEASUREMENT OF QUANTITIES IN
SMAPLES OF BIOLOGICAL ORIGIN -
PRESENTATION OF REFERENCE
MEASUREMENT PROCEDURES**

National Standards
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EUROPEAN STANDARD

EN 12286:1998/A1

NORME EUROPÉENNE

EUROPÄISCHE NORM

May 2000

ICS 11.100

English version

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

Dispositifs médicaux de diagnostic in vitro - Mesure des
grandeurs dans des échantillons d'origine biologique -
Présentation des modes opératoires de mesure de
référence

In-vitro-Diagnostika - Messung von Größen in Proben
biologischen Ursprungs - Darstellung von
Referenzmeßverfahren

This amendment A1 modifies the European Standard EN 12286:1998; it was approved by CEN on 9 April 2000.

CEN members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for inclusion of this amendment into the relevant national standard without any alteration. Up-to-date lists and bibliographical references concerning such national standards may be obtained on application to the Central Secretariat or to any CEN member.

This amendment 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 Central Secretariat 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, Netherlands, Norway, Portugal, Spain, Sweden, Switzerland and United Kingdom.



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

Central Secretariat: rue de Stassart, 36 B-1050 Brussels

Foreword

This Amendment EN 12286:1998/A1:2000 to the EN 12286:1998 has been prepared by Technical Committee CEN/TC 140 "In vitro diagnostic medical devices", the secretariat of which is held by DIN.

This Amendment to the European Standard EN 12286:1998 shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by November 2000, and conflicting national standards shall be withdrawn at the latest by November 2000.

This Amendment to the European Standard EN 12286:1998 has been prepared under a mandate given to CEN by the European Commission and the European Free Trade Association, and supports essential requirements of EU Directive(s).

For relationship with EU Directive(s), see informative Annex ZA, which is an integral part of this standard.

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, Iceland, Ireland, Italy, Luxembourg, Netherlands, Norway, Portugal, Spain, Sweden, Switzerland and the United Kingdom.

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