SLOVENSKI STANDARD

SIST EN 12286:2000/A1:2000

01-november-2000

Diagnostiļ ni medicinski pripomoļ ki in vitro - Merjenje koliļ in v vzorcih biološkega izvora - Predstavitev referenļ nih merilnih postopkov

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

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

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

Ta slovenski standard je istoveten z: **EN 12286:1998/A1:2000**

ICS:

11.100.10	Diagnostiļ ni preskusni sistemi in vitro	In vitro diagnostic test systems

SIST EN 12286:2000/A1:2000 **en**

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN 12286:1998/A1

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

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Ref. No. EN 12286:1998/A1:2000 E

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.

Annex ZA (informative)

Clauses of this European Standard addressing essential requirements or other provisions of EU Directives

This European Standard 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 98/79/EC.

WARNING: Other requirements and other EU Directives may be applicable to the product(s) falling within the scope of this standard.

The following clauses of this standard, as detailed in Table ZA.1, are likely to support requirements of Directive 98/79/EC.

Compliance with these clauses of this standard provides one means of conforming with the specific essential requirements of the Directive concerned and associated EFTA regulations.

Table ZA.1: Correspondence between this European Standard and Directive 98/79/EC

Clause/sub-clause of this European Standard	Corresponding essential requirement of Directive 98/79/EC	Qualifying remarks/Notes
3.7	A.3, B.8.7 (h)	
3.8	A.3, B.8.7 (h)	
3.9	A.3, B.8.7 (h)	
4	A.3, B.4.1	
Annex A	A.3	