EESTI STANDARD EVS-EN 13532:2002

Üldnõuded in vitro diagnostilistele enesekontrolli meditsiiniseadmetele

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

EESTI STANDARDIKESKUS

EESTI STANDARDI EESSÕNA **NATIONAL FOREWORD**

Käesolev Eesti standard EVS-EN 13532:2002 sisaldab Euroopa standardi EN 13532:2002 ingliskeelset teksti. Käesolev dokument on jõustatud 16.05.2002 ja selle kohta on avaldatud teade Eesti standardiorganisatsiooni ametlikus väljaandes. Standard on kättesaadav Eesti standardiorganisatsioonist.	This Estonian standard EVS-EN 13532:2002 consists of the English text of the European standard EN 13532:2002. This document is endorsed on 16.05.2002 with the notification being published in the official publication of the Estonian national standardisation organisation. The standard is available from Estonian standardisation organisation.

Käsitlusala: This European Standard specifies general requirements for in vitro diagnostic medical devices (IVD MDs) for self-testing in order to ensure that IVD MDs for self-testing are safe and suitable for the purposes as specified by the manufacturer. This standard does not address medical aspects of IVD MDs for self-testing.	**Scope:** This European Standard specifies general requirements for in vitro diagnostic medical devices (IVD MDs) for self-testing in order to ensure that IVD MDs for self-testing are safe and suitable for the purposes as specified by the manufacturer. This standard does not address medical aspects of IVD MDs for self-testing.

ICS 11.100

Võtmesõnad: definition, definitions, diagnosis, diagnosis (medical), diagnostic equipment, in vitro, in-vitro diagnostic, labelling, labelling (process), marking, medical sciences, medicine, product informations, reagents, self-testing, specification (approval), specifications

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN 13532

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
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Ref. No. EN 13532:2002 E

Foreword

This document EN 13532 has been prepared by Technical Committee CEN/TC 140 "In vitro diagnostic medical devices", the secretariat of which is held by DIN.

This European Standard shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by October 2002, and conflicting national standards shall be withdrawn at the latest by October 2002.

This document 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 document.

This standard includes a Bibliography.

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, Malta, Netherlands, Norway, Portugal, Spain, Sweden, Switzerland and the United Kingdom.

1 Scope

This European Standard specifies general requirements for in vitro diagnostic medical devices (IVD MDs) for self-testing in order to ensure that IVD MDs for self-testing are safe and suitable for the purposes as specified by the manufacturer.

This standard does not address medical aspects of IVD MDs for self-testing.

2 Normative references

This European Standard incorporates by dated or undated reference, provisions from other publications. These normative references are cited at the appropriate places in the text, and the publications are listed hereafter. For dated references, subsequent amendments to or revisions of any of these publications apply to this European Standard only when incorporated in it by amendment or revision. For undated references the latest edition of the publication referred to applies (including amendments).

EN 376, *Information supplied by the manufacturer with in vitro diagnostic reagents for self-testing.*

EN 592, *Instructions for use for in vitro diagnostic instruments for self-testing.*

EN 1658, *Requirements for marking of in vitro diagnostic instruments.*

EN 13612, *Performance evaluation of in vitro diagnostic medical devices.*

EN 61010-1:2001, *Safety requirements for electrical equipment for measurement, control and laboratory use – Part 1: General requirements (IEC 61010-1:2001).*

EN 61326, *Electrical equipment for measurement, control and laboratory use – EMC requirements (IEC 61326:1997).*

3 Terms and definitions

For the purposes of this European Standard, the following terms and definitions apply.

3.1
in vitro diagnostic medical device
any medical device which is a reagent, reagent product, calibrator, control material, kit, instrument, apparatus, equipment or system, whether used alone or in combination, intended by the manufacturer to be used in vitro for the examination of specimens, including blood and tissue donations, derived from the human body, solely or principally for the purpose of providing information concerning a physiological or pathological state, or concerning congenital abnormality, or to determine the safety and compatibility with potential recipients, or to monitor therapeutic measures

NOTE 1 A specimen receptacle, whether vacuum-type or not, specifically intended by its manufacturer for the primary containment and preservation of specimens derived from the human body for the purpose of in vitro diagnostic examination is considered to be an in vitro diagnostic medical device.

NOTE 2 Products for general laboratory use are not in vitro diagnostic medical devices unless such products, in view of their characteristics, are specifically intended by their manufacturer to be used for in vitro diagnostic examination.

3.2
lay person
individual who does not have specific medical education
[EN 376:2002]

3.3
marking
inscription, in writing or as a graphical symbol, permanently affixed to a product

NOTE Examples for inscriptions are manufacturer's or distributor's trademark, model or type number, identification of intended functions, supply voltage, particular warnings.