In vitro kasutatavad diagnostikasüsteemid. Juhend standardite EN 29001 ja EN 46001 ning standardite EN 29002 ja EN 46002 rakendamiseks in vitro kasutatavate meditsiinivahendite korral

In vitro diagnostic systems - Guidance on the application of EN 29001 and EN 46001 and of EN 29002 and EN 46002 for in vitro diagnostic medical devices

EESTI STANDARDI EESSÕNA

NATIONAL FOREWORD

Käesolev Eesti standard EVS-EN 928:1999 sisaldab Euroopa standardi EN 928:1995 ingliskeelset teksti. Käesolev dokument on jõustatud 12.12.1999 ja selle kohta on avaldatud teade Eesti standardiorganisatsiooni ametlikus väljaandes. Standard on kättesaadav Eesti standardiorganisatsioonist.	This Estonian standard EVS-EN 928:1999 consists of the English text of the European standard EN 928:1995. This document is endorsed on 12.12.1999 with the notification being published in the official publication of the Estonian national standardisation organisation. The standard is available from Estonian standardisation organisation.

Käsitlusala: Käesolev standard esitab juhiseid in vitro diagnostikasüsteemide tootja kohta kehtivate standardite EN 29001 ja EN 46001 ning EN 29002 ja EN 46002 ellurakendamiseks. Standardi eesmärgiks on pakkuda paremat arusaamist kõnealustest standarditest enestest ja ka abi nende kasutamisel, kas sellise kvaliteedisüsteemi teostamisel või hindamisel.	**Scope:**

ICS 11.100

Võtmesõnad: bioloogiline proov, kvaliteeditagamine, kvaliteet, meditsiin, meditsiiniaparatuur, tehnilised andmed, tootmine

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Descriptors: In vitro diagnostic systems, medical devices, quality management.

English version

In vitro diagnostic systems

Guidance on the application of EN 29001 and EN 46001 and of EN 29002 and EN 46002 for *in vitro* diagnostic medical devices

Systèmes d'analyses médicales in vitro; guide d'application des EN 29001 et EN 46001, et EN 29002 et EN 46002 pour les dispositifs médicaux de diagnostic in vitro

In-vitro-Diagnostik/Diagnostika; Leitfaden für die Anwendung von EN 29001 und EN 46001 sowie EN 29002 und EN 46002 für Medizinprodukte für die In-vitro-Diagnose

This European Standard was approved by CEN on 1995-03-14.

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 Central Secretariat 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 Central Secretariat has the same status as the official versions.

CEN members are the national standards bodies of Austria, Belgium, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Luxembourg, Netherlands, Norway, Portugal, Spain, Sweden, Switzerland and United Kingdom.

CEN

European Committee for Standardization
Comité Européen de Normalisation
Europäisches Komitee für Normung

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

Foreword

This European Standard has been prepared by Technical Committee CEN/TC 140 'In vitro diagnostic systems', the Secretariat of which is held by DIN.

This European Standard has been prepared under a mandate given to CEN by the Commission of the European Communities and the European Free Trade Association and supports essential requirements of the relevant EC Directives.

This European Standard needs to be considered in conjunction with both the EN 29000 series of standards and the EN 46000 series of standards. It is intended to provide guidance for industry, certifying bodies and regulatory bodies.

This European Standard shall be given the status of a national standard, either by publication of an identical text or by endorsement, and conflicting national standards withdrawn, by May 1996 at the latest.

In accordance with the CEN/CENELEC Internal Regulations, the following countries are bound to implement this European Standard:

Austria, Belgium, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Luxembourg, Netherlands, Norway, Portugal, Spain, Sweden, Switzerland and United Kingdom.

Contents

Introduction

This European Standard has been prepared to give guidance to organizations providing in vitro diagnostic medical devices (IVDs) and wishing to comply with EN 29001 and EN 29002 and the particular requirements for medical devices in EN 46001 and EN 46002. This European Standard needs to be read in conjunction with the relevant standards with which compliance is sought. This European Standard is not a substitute for, or a supplement to, EN 29004 which has its own very distinct relationship with the EN 29000 series of standards.

This European Standard does not add any requirements to those in the EN 29000 series. Care should be taken that the guidance, which may suggest various methods of providing assurance, is not used in place of, or as additional requirements to those given in the EN 29000 series.

The aim of this European Standard is primarily to assist suppliers, purchasers and certification bodies to achieve a uniform interpretation of EN 29001 and EN 29002 and of EN 46001 and EN 46002 by presenting familiar concepts under the relevant clauses from these standards. It attempts to explain what should be done to fulfil customer needs and is not only a guide for quality assessors.

The combination of EN 29001 and EN 46001 and of EN 29002 and EN 46002 embrace the principles of Good Manufacturing Practice (GMP) which have been used in the medical device industry for a number of years.

1 Scope

This European Standard provides guidance on the implementation of EN 29001 and EN 46001 and of EN 29002 and EN 46002 as applied to the manufacturer of IVDs. It is aimed at affording a better understanding of the standards themselves as well as assistance in their use, either in implementing or evaluating such a quality system. The guidance given is not intended to be exhaustive, but to highlight important aspects to which attention should be drawn.

The adoption of systems other than those described in this European Standard is not to be regarded as a non-compliance with EN 29001 and EN 29002 and/or the particular requirements in EN 46001 and EN 46002.

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.

EN 29001 : 1987	Quality systems – Model for quality assurance in design/development, production, installation and servicing
EN 29002 : 1987	Quality systems – Model for quality assurance in production and installation
EN 29004 : 1987	Quality management and quality system elements – Guidelines
EN 46001 : 1993	Quality systems – Medical devices – Particular requirements for the application of EN 29001
EN 46002 : 1993	Quality systems – Medical devices – Particular requirements for the application of EN 29002

3 Definitions

For the purposes of this standard, the definitions given in EN 46001 : 1993 and EN 46002 : 1993 apply.

4 Guidance on quality system requirements

[refers to clauses 4 of EN 29001 : 1987 and EN 46001 : 1993 and to clauses 4 of EN 29002 : 1987 and EN 46002 : 1993]

4.1 Management responsibility

[refers to clauses 4.1 of EN 29001 : 1987 and EN 46001 : 1993 and to clauses 4.1 of EN 29002 : 1987 and EN 46002 : 1993]