EESTI STANDARD EVS-EN 13612:2002

In vitro diagnostiliste seadmete jõudluse hindamine

Performance evaluation of in vitro diagnostic medical devices

EESTI STANDARDIKESKUS

EESTI STANDARDI EESSÕNA

NATIONAL FOREWORD

Käesolev Eesti standard EVS-EN 13612:2002 sisaldab Euroopa standardi EN 13612:2002+AC:2002 ingliskeelset teksti. Käesolev dokument on jõustatud 06.08.2002 ja selle kohta on avaldatud teade Eesti standardiorganisatsiooni ametlikus väljaandes. Standard on kättesaadav Eesti standardiorganisatsioonist.	This Estonian standard EVS-EN 13612:2002 consists of the English text of the European standard EN 13612:2002+AC:2002. This document is endorsed on 06.08.2002 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 applies to the performance evaluation of in vitro diagnostic medical devices (IVD MDs) including IVD MDs for self-testing. It specifies the responsibilities and general requirements for the planning, conduct, assessment and documentation of a performance evaluation study by the manufacturer. It does not apply to specific evaluation plans for certain IVD MDs or a specific use. Where a manufacturer maintains a quality system this standard addresses the compliance with "design validation" and "design changes" as described in EN ISO 9001, EN 46001 and EN 928 especially considering the nature and use of IVD MDs. In particular, this standard applies to IVD MDs to - show evidence to notified bodies and national authorities by results of a performance evaluation that the IVD MD performs as claimed by the manufacturer, - establish adequate performance evaluation data originating from appropriate studies or resulting from available literature, and to - satisfy the requirements of a quality system for design validation.	**Scope:** This European Standard applies to the performance evaluation of in vitro diagnostic medical devices (IVD MDs) including IVD MDs for self-testing. It specifies the responsibilities and general requirements for the planning, conduct, assessment and documentation of a performance evaluation study by the manufacturer. It does not apply to specific evaluation plans for certain IVD MDs or a specific use. Where a manufacturer maintains a quality system this standard addresses the compliance with "design validation" and "design changes" as described in EN ISO 9001, EN 46001 and EN 928 especially considering the nature and use of IVD MDs. In particular, this standard applies to IVD MDs to - show evidence to notified bodies and national authorities by results of a performance evaluation that the IVD MD performs as claimed by the manufacturer, - establish adequate performance evaluation data originating from appropriate studies or resulting from available literature, and to - satisfy the requirements of a quality system for design validation.

ICS 11.100

Võtmesõnad: diagnosis, diagnosis (medical), diagnostic equipment, efficiency, evaluations, in vitro, in-vitro diagnostic, laboratory medicine, marking, medical sciences, medicine, product informations, quality assessment, quality assurance, reagents, self-testing, verification

EUROPEAN STANDARD

NORME EUROPÉENNE

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English version

Performance evaluation of in vitro diagnostic medical devices

Détermination des performances des dispositifs médicaux pour diagnostic in vitro

Leistungsbewertung von In-vitro-Diagnostika

This European Standard was approved by CEN on 5 January 2002.

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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Foreword

This document EN 13612:2002 has been prepared by Technical Committee CEN/TC 140 "In vitro diagnostic medical devices", the secretariat of which is held by DIN.

The European Diagnostic Manufacturers Association (EDMA) has contributed to its preparation.

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 September 2002, and conflicting national standards shall be withdrawn at the latest by September 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.

Annex ZA is for information only.

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.

Introduction

Directive 98/79/EC on in vitro diagnostic medical devices (IVD MDs) requires in Annex III, section 3, indent 11 and section 6.1, in Annex IV, section 3.2 c) and in Annex V, section 3, that the manufacturer provides evidence in his technical documentation that the IVD MD performs as claimed, whether these claims are of a technical, analytical or diagnostic nature. Such evidence can be shown by data already available to the manufacturer or by scientific literature or by data originating from performance evaluation studies in a clinical or other appropriate environment in accordance with the intended use.

If a performance evaluation study is necessary and appropriate to support performance claims of the IVD MD, this standard describes how the manufacturer can fulfil his obligation to conduct a scientifically sound performance evaluation study. The evaluation plan is adapted to the nature of the IVD MD and its intended use, taking into account the various recommendations given in standards and scientific literature.

Considering the broad range of IVD MDs covered by Directive 98/79/EC and taking into account that, up to now, there is no uniformly applicable document, it is the purpose of this standard to present the common elements to be considered for a performance evaluation. The applicability of many items described will depend on the level of complexity of the IVD MD.

At the time of drafting this standard it was envisaged that the European Commission would publish a number of Common Technical Specifications (CTSs) which would be relevant to Directive 98/79/EC on in vitro diagnostic medical devices. It was further envisaged that these would be referenced in the Official Journal of the European Communities. In particular these CTSs will apply to in vitro diagnostic medical devices falling into list A of annex II of the Directive 98/79/EC and possibly a number of in vitro diagnostic medical devices in list B of annex II of the same directive. Manufacturers should therefore take these CTSs into account within the context of Article 5 “Reference to standards”, of the Directive 98/79/EC.

1 Scope

This European Standard applies to the performance evaluation of in vitro diagnostic medical devices (IVD MDs) including IVD MDs for self-testing. It specifies the responsibilities and general requirements for the planning, conduct, assessment and documentation of a performance evaluation study by the manufacturer. It does not apply to specific evaluation plans for certain IVD MDs or a specific use.

NOTE For a selection of publications on specific evaluation plans see Bibliography.

Where a manufacturer maintains a quality system this standard addresses the compliance with "design validation" and "design changes" as described in EN ISO 9001, EN 46001 and EN 928 especially considering the nature and use of IVD MDs.

In particular, this standard applies to IVD MDs to

- show evidence to notified bodies and national authorities by results of a performance evaluation that the IVD MD performs as claimed by the manufacturer,

- establish adequate performance evaluation data originating from appropriate studies or resulting from available literature, and to

- satisfy the requirements of a quality system for design validation.

2 Terms and definitions

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

2.1
co-ordinator of a performance evaluation study
person empowered by the manufacturer with responsibility for the entire performance evaluation study of an in vitro diagnostic medical device

2.2
drop out
specimen or proband that had been selected for a performance evaluation study, but cannot be investigated as planned

2.3
evaluation plan
description of a planned performance evaluation study

2.4
evaluation report
description of and conclusions from a performance evaluation study

2.5
investigator
person responsible for the execution of the performance evaluation at a certain location

2.6
lay person
individual who does not have specific medical education
[EN ISO 9000:2000, 3.8.5]