SLOVENSKI STANDARD

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Ovrednotenje diagnostiļ nih medicinskih pripomoļ kov lastnosti in vitro

Performance evaluation of in vitro diagnostic medical devices

Leistungsbewertung von In-vitro-Diagnostika

Evaluation des performances des dispositifs médicaux de diagnostic in vitro

Ta slovenski standard je istoveten z: EN 13612:2002

ICS:

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

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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.

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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of an identical text or by endorsement, at the latest by September 2002, and conflicting national standards shall be withdrawn at the latest by September 2002.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]

2.7
performance claim
specification in regard to the performance of an in vitro diagnostic medical device laid down in the information supplied by the manufacturer

2.8
performance evaluation
investigation of the performance of an in vitro diagnostic medical device based upon data already available, scientific literature and/or performance evaluation studies

2.9
performance evaluation study
investigation of an in vitro diagnostic medical device intended to validate the performance claims under the anticipated conditions of use

2.10
performance of an in vitro diagnostic medical device
set of properties of an in vitro diagnostic medical device related to its suitability for the intended purpose

2.11
performance study records
documentation of the experimental steps during the performance evaluation study and results obtained

2.12
proband of a performance evaluation study
individual being part of a study in order to obtain specimen(s) with defined characteristics to be used for the performance evaluation study

2.13
tutor
person responsible for the supervision of lay persons involved in the performance evaluation study

2.14
validation
confirmation , through the provision of objective evidence that the requirements for a specific intended use or application have been fulfilled

NOTE 1 The term “validated” is used to designate the corresponding status.

NOTE 2 The use conditions for validation can be real or simulated.

[ISO 9000, 3.8.5]

3 General requirements for the performance evaluation

3.1 Responsibilities and resources

The manufacturer takes the responsibility for the initiation and/or the conduct of a performance evaluation study. He shall define the responsibility and the interrelation of all personnel who manage and conduct the performance evaluation of IVD MDs, particularly for personnel who need the organisational freedom and authority to

a) assess the validity of test results and data already available;

b) specify performance claims which shall be further examined or confirmed;

c) specify and document the evaluation plan and the test procedures;

d) prepare the evaluation report.

The manufacturer shall appoint a co-ordinator with overall responsibility of the performance evaluation study. The co-ordinator shall himself assure that adequate resources are available. The investigator shall ensure that the evaluation plan is followed at his location and that the study is appropriately reviewed from an ethical point of view.

3.2 Documentation

The documentation of the performance evaluation study shall contain the files relating to clauses 3 to 7 of this standard and shall be part of the technical documentation of the IVD MD.

3.3 Final assessment and review

The co-ordinator shall assess and document which performance claims are met, state whether claims are not met and give recommendations for corrective actions, where necessary.

The responsible management of the manufacturer shall make sure that the results of the performance evaluation study and the recommendations for corrective actions are carefully considered and properly documented before issuing a declaration of conformity.

4 Organisation of a performance evaluation study

4.1 Preconditions

Before starting a performance evaluation study it shall be ensured by the co-ordinator that

a) the performance claims of the IVD MD which are the subject of the study are specified;

b) the IVD MD has been manufactured under controlled production processes and conditions;

c) the IVD MD to be evaluated meets the quality control release specifications;

d) a sufficient number of samples of the IVD MD can be provided during the entire period of the performance evaluation study;

e) all legal requirements for performance evaluation studies are met;

f) the investigator(s) is (are) adequately skilled and trained to conduct the study and the necessary resources are available.

4.2 Evaluation plan

The evaluation plan shall state the purpose on scientific, technical or medical grounds, the scope of the evaluation, the structure and organization of the study and the number of devices concerned.

Defining the objective of the study, the co-ordinator shall have assessed which performance claims are already verified by data or scientific literature.