BRITISH STANDARD

BS EN
13612:2002

Performance evaluation of in vitro diagnostic medical devices

The European Standard EN 13612:2002 has the status of a British Standard

ICS 11.100

National foreword

This British Standard is the official English language version of EN 13612:2002.

The UK participation in its preparation was entrusted to Technical Committee CH/69, In vitro diagnostic systems, which has the responsibility to:

— aid enquirers to understand the text;

— present to the responsible European committee any enquiries on the interpretation, or proposals for change, and keep the UK interests informed;

— monitor related international and European developments and promulgate them in the UK.

A list of organizations represented on this committee can be obtained on request to its secretary.

Cross-references

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This British Standard, having been prepared under the direction of the Health and Environment Sector Policy and Strategy Committee, was published under the authority of the Standards Policy and Strategy Committee on 7 May 2002

Summary of pages

This document comprises a front cover, an inside front cover, the EN title page, pages 2 to 15 and a back cover.

The BSI copyright date displayed in this document indicates when the document was last issued.

Amendments issued since publication

Amd. No.	Date	Comments

ISBN 0 580 39650 9

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN 13612

March 2002

ICS 11.100

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.

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EUROPÄISCHES KOMITEE FÜR NORMUNG

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Ref. No. EN 13612:2002 E

Contents

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of an identical text or by endorsement, at the latest by September 2002, and conflicting national standards shall be withdrawn at the latest by September 2002.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

The evaluation plan shall be designed to minimise the requirements for invasive sampling. In the case of IVD MDs for self-testing it shall be ensured that the evaluation plan is appropriate and acceptable to users and the information provided shall be clear and easily understood.

The evaluation plan shall specify

a) that the investigator(s) is (are) adequately skilled and trained to use the IVD MD;

b) the list of laboratories or other institutions taking part in the performance evaluation study; for self-testing, the location and number of lay persons involved;

c) the time-table;

d) the necessary minimum number of probands from whom specimens are collected by invasive procedures in order to adequately assess the performance of the IVD MD;

e) instructions for use including a description of the conditions of use;

f) the performance claims (e.g. analytical sensitivity, diagnostic sensitivity, analytical specificity, diagnostic specificity, accuracy, repeatability, reproducibility) to be validated;

g) the format of performance study records.

4.3 Sites and resources

In general, the performance study procedure(s) shall be carried out under conditions reflecting the relevant intended conditions of use.

The co-ordinator shall take the responsibility for the proper conduct of the performance evaluation study at all sites. All investigators shall be named.

The co-ordinator shall ensure adequate competence and skill at all sites involved and that the necessary resources are available.

Where lay persons are involved in a performance evaluation study of an IVD MD for self-testing, the location of the study and the number of persons shall be given. The co-ordinator shall specify the criteria for the selection of a representative panel.

Especially for studies involving lay persons it shall be ensured that these persons do not receive additional information on the use of the IVD MD apart from that which is provided with the IVD MD when it is placed on the market because the comprehension of the manufacturer's instructions for use is one of the important aspects of the study. It shall also be ensured that the untrained person(s) do not receive any additional information or help, e. g. from a tutor, other than the training specified and provided by the manufacturer in the instructions for use.

4.4 Basic design information

The co-ordinator shall provide the investigator(s) with sufficient information in order to understand the function and application of the IVD MD and, where necessary, the investigator shall make himself familiar with the IVD MD and its application. The information provided shall include a statement that the device in question conforms with the requirements of the Directive 98/79/EC apart from those to be evaluated.

4.5 Experimental design

The experimental procedures to validate each performance claim subject to the performance evaluation study shall be documented in the evaluation plan.

Special consideration in performance evaluation studies of reagents/kits shall be given, where applicable, to the following:

– specification of type (e.g. serum, plasma, urine) and properties (e.g. concentration range, age and sex of the proband population) of specimens appropriate to the intended use;

– probands to be enrolled;

– suitability, stability and volume of specimens and specimen exclusion criteria;

– blind procedures, where necessary;

– reagent stability;

– inclusion of common interfering factors, caused by specimen condition or the pathological/physiological status of the specimen donor or treatment;

– conditions for use which can be reasonably anticipated; special attention shall be paid to the conditions of use by lay persons;

– selection of an appropriate reference measurement procedure and reference material of higher order, where available;

– determination of the status of specimens (for qualitative tests with a nominal or ordinal scale);

– calibration procedures, including traceability, where appropriate;

– appropriate means of control;

– limitations of the test;

– criteria for re-examination and data exclusion;

– availability of additional information concerning the specimen or donor if follow-up of expected results is required;

– appropriate measures to reduce risk of infection to the user.

Where the study is intended to validate the performance claims of an instrument special consideration shall be given additionally to the following:

– maintenance and cleaning;

– carry-over effects;

– software validation.

NOTE For the investigation of the technical aspects of instruments, other standards can be relevant.

4.6 Performance study records

The performance study records shall

– refer to the experimental procedures in the evaluation plan;

– be unequivocally identifiable;

– contain or refer to all results and related relevant data;

– be part of the technical documentation of the IVD MD.

The protection of all confidential data shall be ensured.

4.7 Observations and unexpected outcomes

Special attention shall be paid to observations and unexpected outcomes, e. g. drop outs, outliers, instability of sample or reagent signal etc., non-reproducibility, non-correlation of results to the reference or to the diagnostic pattern, defects or breakdowns, software errors, or error signals.

Any deviation from the defined procedures shall be recorded. In the case of IVD MDs for self-testing, the investigator or tutor shall duly note any difficulty or question a user may have and any deviation from the mode of application of the IVD MD as described by the manufacturer.

Any such observation shall be properly recorded. The co-ordinator shall, together with the investigator, trace the cause whenever possible. The result shall be recorded and shall be part of the evaluation report.

Where the validity of the examinations already performed may be questionable because of an identified source of error the tests shall be repeated after exclusion of that cause.

Where a misuse or misinterpretation of the instructions for use has been the cause and where an unexpected risk inherent to the product design or the mode of application has been identified this shall be clearly stated.

The proposals of the investigator(s) and the co-ordinator for any improvement of the IVD MD and/or its application shall be recorded.

4.8 Evaluation report

The co-ordinator shall establish an evaluation report. It shall contain a description of the study, an analysis of the results together with a conclusion on the performance claims investigated.

The report shall also discuss any unexpected outcomes which have occurred. It shall identify the cause whenever possible and give recommendations for corrective actions to be taken, where necessary.

If several studies have been conducted for one IVD MD, a single summarizing report may be established.

5 Modifications during the performance evaluation study

Where the manufacturing process has been changed it shall be checked whether the performance claims of the IVD MD still conform to those which had been set initially. Otherwise the validity of the examinations already performed shall be questioned and the evaluation plan shall be revised accordingly.

Where design changes are introduced, the evaluation plan shall be revised.

6 Re-evaluation

In case of changes to the design or manufacturing process of the IVD MD, the performance evaluation study shall be repeated as far as necessary, to ensure that the intended use and the performance claims of the IVD MD placed on the market are adequately evaluated.

This re-evaluation may refer to documented results of a preceding evaluation insofar as these are considered valid and transferable after critical review.

7 Protection and safety of probands

The removal, collection and use of tissues, cells and substances of human origin is governed, in relation to ethics, by the principles laid down in the Convention of the Council of Europe for the protection of human rights and dignity of the human being with regard to the application of biology and medicine and by any national regulations on this matter.

In any case, the results obtained from a specimen by means of the IVD MD under evaluation shall not be used for other purposes than for performance evaluation, unless ethical reasons, fully supported by a responsible medical professional, suggest the contrary. In such a case the medical professional assumes complete responsibility.

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 the 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 the EU 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 EU Directive 98/79/EC

Clauses/subclauses of this European Standard	Essential requirements of EU Directive 98/79/EC	Qualifying remarks/notes
4.2	A.3	
4.3	B.7, B.8	
4.4	A.3	
4.5	A.3, A.4, B.2, B.4.1, B.6.1	

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[1]) ECCLS = European Committee for Clinical Laboratory Standards
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