SLOVENSKI STANDARD

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Splošne zahteve za diagnostiļne pripomoļke in vitro za samopreskuļanje

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

Allgemeine Anforderungen an In-vitro-Diagnostika zur Eigenanwendung

Exigences générales relatives aux dispositifs médicaux de diagnostic in vitro pour auto-test

Ta slovenski standard je istoveten z: **EN 13532:2002**

ICS:

11.100.10	Diagnostiļni preskusni sistemi in vitro	In vitro diagnostic test systems

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EUROPEAN STANDARD

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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
COMITÉ EUROPÉEN DE NORMALISATION
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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of an identical text or by endorsement, at the latest by October 2002, and conflicting national standards shall be withdrawn at the latest by October 2002.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.

3.4
permanently affixed
removable only with a tool or by appreciable force and able to withstand the effects of temperature, rubbing, common solvents, reagents, and vapours encountered during normal use

3.5
self-testing
use in the home or similar environments by a lay person who will relate the result of the test to him- or herself [EN 376:2002]

4 Design criteria

4.1 Ergonomic and human factor aspects

The design of IVD MDs for self-testing shall take the following ergonomic and human factors into consideration:

– identification of intended users;

– ease of operation;

– ease of user maintenance;

– readability of the test results;

– ease of interpretation of the instructions for use;

– ease of verification by the user of the correct functioning of the IVD MD for self-testing;

– reasonably foreseeable variations in the way in which the user performs the test;

– reasonably foreseeable variations in the environment in which the test is performed;

– reasonably foreseeable misuse.

When taking these factors into account, consideration shall be given to potential limitations in skills and capabilities of users for whom the IVD MD for self-testing is intended.

4.2 Electromagnetic compatibility

EN 61326 shall apply, if relevant.

4.3 Protection against electric shock

EN 61010-1:2001, clause 6, shall apply, if relevant.

4.4 Protection against mechanical hazards

EN 61010-1:2001, clause 7, shall apply, if relevant.

4.5 Mechanical resistance to shock, vibration and impact

EN 61010-1:2001, clause 8, shall apply, if relevant.

4.6 Equipment temperature exposure limits

EN 61010-1:2001, clause 10, shall apply.

4.7 Resistance to heat

EN 61010-1:2001, clause 10 as well as 12.3 and 12.4, shall apply.

Additionally, it shall be taken into account that heat may be generated by natural sunlight and other visible light sources.

4.8 Resistance to moisture and liquids

EN 61010-1:2001, 11.1, 11.2 and 11.3, shall apply.

4.9 Protection against liberated gases, explosion and implosion

EN 61010-1:2001, 13.1 and 13.2, shall apply, if relevant.

4.10 Components

EN 61010-1:2001, 14.1, 14.4, 14.5 and 14.6, shall apply.

4.11 Risk analysis

The manufacturer shall decide on the acceptability of potential risk of such factors as:

– unforeseen use of the IVD MD for self-testing in a potentially unsuitable environment (e. g. travel, hotel);

– limitations of skills and means available to lay users;

– limitations of specified performance characteristics;

– probability of occurrence of failure;

– consequence of a failure;

– inappropriate disposal.

NOTE This subclause refers to EN 1441. This standard does not stipulate levels of acceptability which, because they are determined by a multiplicity of factors, cannot by their nature be set down in such a standard. This standard is not intended to give detailed guidance on management of risks. Furthermore, it is not intended to cover decision-making processes regarding assessment of the indications and contra-indications for the use of a particular IVD MD for self-testing.

4.12 Design change

Changes to the design of an IVD MD for self-testing which are made after it has been put onto the market and which affect

– the specifications;

– the performance;

– the marking and information supplied by the manufacturer if ignoring such changes could lead to erroneous results;

– aspects of safety of the user or a third party

shall be regarded as significant. Such changes shall be submitted to risk analysis and evaluation.

5 Markings and information supplied by the manufacturer

5.1 Markings and labels of IVD MDs for self-testing

Where an IVD MD for self-testing involves the use of an instrument, the marking of the instrument shall be in accordance with EN 1658. In addition, the IVD instruments for self-testing shall bear the following markings, if appropriate, e. g. if not noted in the instructions for use of the instrument or on the label or in the instructions for use of the reagents necessary to perform the respective self-testing:

– intended purpose;

– a statement that the instrument is intended for self-testing;

– a reference to the instructions for use.

Where an IVD MD for self-testing involves the use of a reagent, reagent product, calibrator, control material, kit and/or other consumables, these elements shall be labelled according to EN 376.

5.2 Instructions for use of IVD MDs for self-testing

Any instructions for use of instruments shall be in accordance with the requirements given in EN 592.

Any instructions for use of reagents, reagent products, calibrators, control materials, kits and/or other consumables shall be in accordance with the requirements given in EN 376.

6 Performance evaluation

EN 13612 shall apply.

7 User verification

User verification, if reasonably possible, shall allow the user to check at the time of use

– correct functioning of the IVD MD for self-testing, i. e. system control,

– correct execution of the test including sequence of the procedural steps.

NOTE "At the time of use" means immediately before, during, or immediately after the execution of the respective self-test.

User verification shall be integrated into the test wherever reasonably possible. User verification should give unambiguous information. The instructions for use shall clearly and in simple terms state what to do if the verification indicates an invalid result.

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 EU 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 to 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
4.1	B.3.3.1, B.3.6, B.7, B.7.1, B.7.2, B.8.7 (t)	
4.2	B.3.3, B.6.2	
4.3	B.3.3.2, B.6.3, B.6.4.4	
4.4	B.3.3.1, B.6.4	
4.5	B.6.4.2	
4.6	B.3.3.2	
4.7	B.3.3.2	
4.8	B.1.2	
4.9	B.3.4	
4.10	B.3.1	
4.11	A.1, A.2, A.4, A.5	
5.1	B.8, B.8.4	
5.2	B.8, B.8.7,	
7	B.7.2, B.8.7 (t)	