ROPEAN STANDARD
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ROPÄISCHE NORM

EN 13532

April 2002

1.100

English version

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

nces générales relatives aux dispositifs médicaux de
iagnostic in vitro destinés à des auto-diagnostics

Allgemeine Anforderungen an In-vitro-
Eigenanwendung

uropean Standard was approved by CEN on 27 December 2001.

nembers are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for giving
ard the status of a national standard without any alteration. Up-to-date lists and bibliographical references concerni
ards may be obtained on application to the Management Centre or to any CEN member.

uropean Standard exists in three official versions (English, French, German). A version in any other language mad
the responsibility of a CEN member into its own language and notified to the Management Centre has the same st
ns.

nembers are the national standards bodies of Austria, Belgium, Czech Republic, Denmark, Finland, France, Germa
d, Ireland, Italy, Luxembourg, Malta, Netherlands, Norway, Portugal, Spain, Sweden, Switzerland and United Kingd

EUROPEAN COMMITTEE FOR STANDARDIZATION
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EUROPÄISCHES KOMITEE FÜR NORMUNG

Management Centre: rue de Stassart, 36 B-1050 Brussels

Ref. No.

word

ocument EN 13532 has been prepared by Technical Committee CEN/TC 140 "In vitro diagnostic m
s", the secretariat of which is held by DIN.

uropean Standard shall be given the status of a national standard, either by publication of an iden
orsement, at the latest by October 2002, and conflicting national standards shall be withdrawn a
ober 2002.

ocument has been prepared under a mandate given to CEN by the European Commission and th
ade Association, and supports essential requirements of EU Directive(s).

ationship with EU Directive(s), see informative annex ZA, which is an integral part of this documen

ndard includes a Bibliography.

ng to the CEN/CENELEC Internal Regulations, the national standards organizations of th
es are bound to implement this European Standard: Austria, Belgium, Czech Republic, Denma
Germany, Greece, Iceland, Ireland, Italy, Luxembourg, Malta, Netherlands, Norway, Portu
n, Switzerland and the United Kingdom.

Scope

European Standard specifies general requirements for in vitro diagnostic medical devices
testing in order to ensure that IVD MDs for self-testing are safe and suitable for the purposes as s
ufacturer.

standard does not address medical aspects of IVD MDs for self-testing.

Normative references

European Standard incorporates by dated or undated reference, provisions from other public
native references are cited at the appropriate places in the text, and the publications are listed herea
ences, subsequent amendments to or revisions of any of these publications apply to this European
incorporated in it by amendment or revision. For undated references the latest edition of the publi
plies (including amendments).

76, *Information supplied by the manufacturer with in vitro diagnostic reagents for self-testing.*

92, *Instructions for use for in vitro diagnostic instruments for self-testing.*

658, *Requirements for marking of in vitro diagnostic instruments.*

3612, *Performance evaluation of in vitro diagnostic medical devices.*

1010-1:2001, *Safety requirements for electrical equipment for measurement, control and laboratory*
ral requirements (IEC 61010-1:2001).

1326, *Electrical equipment for measurement, control and laboratory use – EMC requirements (IEC*

Terms and definitions

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

ro diagnostic medical device

nedical device which is a reagent, reagent product, calibrator, control material, kit, instrumen
ment or system, whether used alone or in combination, intended by the manufacturer to be used i
nation of specimens, including blood and tissue donations, derived from the human body, solely or
urpose of providing information concerning a physiological or pathological state, or concernir
mality, or to determine the safety and compatibility with potential recipients, or to monitor therapeutic

1 A specimen receptacle, whether vacuum-type or not, specifically intended by its manufacturer for the prima
eservation of specimens derived from the human body for the purpose of in vitro diagnostic examination is cons
diagnostic medical device.

2 Products for general laboratory use are not in vitro diagnostic medical devices unless such products, i
teristics, are specifically intended by their manufacturer to be used for in vitro diagnostic examination.

erson

lual who does not have specific medical education
76:2002]

ing

tion, in writing or as a graphical symbol, permanently affixed to a product

Examples for inscriptions are manufacturer's or distributor's trademark, model or type number, identification
ns, supply voltage, particular warnings.

nently affixed
ble only with a tool or by appreciable force and able to withstand the effects of temperature, rubbin
s, reagents, and vapours encountered during normal use

sting
he home or similar environments by a lay person who will relate the result of the test to him- or h
6:2002]

esign criteria

Ergonomic and human factor aspects

sign of IVD MDs for self-testing shall take the following ergonomic and human factors into considera

entification of intended users;

se of operation;

se of user maintenance;

adability of the test results;

se of interpretation of the instructions for use;

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

asonably foreseeable variations in the way in which the user performs the test;

asonably foreseeable variations in the environment in which the test is performed;

asonably foreseeable misuse.

aking these factors into account, consideration shall be given to potential limitations in skills and ca
r whom the IVD MD for self-testing is intended.

Electromagnetic compatibility

26 shall apply, if relevant.

Protection against electric shock

10-1:2001, clause 6, shall apply, if relevant.

Protection against mechanical hazards

10-1:2001, clause 7, shall apply, if relevant.

Mechanical resistance to shock, vibration and impact

10-1:2001, clause 8, shall apply, if relevant.

Equipment temperature exposure limits

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

Resistance to heat

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

tionally, it shall be taken into account that heat may be generated by natural sunlight and oth
ces.

Resistance to moisture and liquids

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

Protection against liberated gases, explosion and implosion

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

Components

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

Risk analysis

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, h
- 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.

E This subclause refers to EN 1441. This standard does not stipulate levels of acceptability which, be
mined by a multiplicity of factors, cannot by their nature be set down in such a standard. This standard is not
ed guidance on management of risks. Furthermore, it is not intended to cover decision-making proce
ssment of the indications and contra-indications for the use of a particular IVD MD for self-testing.

Design change

nges to the design of an IVD MD for self-testing which are made after it has been put onto the ma
ct

- the specifications;
- the performance;
- the marking and information supplied by the manufacturer if ignoring such changes could lead
esults;

ects of safety of the user or a third party

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

arkings and information supplied by the manufacturer

Markings and labels of IVD MDs for self-testing

an IVD MD for self-testing involves the use of an instrument, the marking of the instrument s
nce with EN 1658. In addition, the IVD instruments for self-testing shall bear the following m
ate, e. g. if not noted in the instructions for use of the instrument or on the label or in the instructions
ents necessary to perform the respective self-testing:

nded purpose;

atement that the instrument is intended for self-testing;

eference to the instructions for use.

n IVD MD for self-testing involves the use of a reagent, reagent product, calibrator, control material,
nsumables, these elements shall be labelled according to EN 376.

nstructions for use of IVD MDs for self-testing

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

uctions for use of reagents, reagent products, calibrators, control materials, kits and/or other con
n accordance with the requirements given in EN 376.

rformance evaluation

2 shall apply.

er verification

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

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

ect execution of the test including sequence of the procedural steps.

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

fication shall be integrated into the test wherever reasonably possible. User verification sh
ous information. The instructions for use shall clearly and in simple terms state what to do if the v
an invalid result.

Annex ZA
(informative)

Clauses of this European Standard addressing essential requirements or provisions of EU Directives

European Standard has been prepared under a mandate given to CEN by the European Comm pean 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) fa scope of this standard.

following clauses of this standard, as detailed in Table ZA.1, are likely to support require irective 98/79/EC.

pliance with these clauses of this standard provides one means of conforming to the spe rements of the Directive concerned and associated EFTA regulations.

Table ZA.1 – Correspondence between this European Standard and EU Directive 98/7

uses/subclauses of this opean Standard	Essential requirements of EU Directive 98/79/EC	Qualifying remark
	B.3.3.1, B.3.6, B.7, B.7.1, B.7.2, B.8.7 (t)	
	B.3.3, B.6.2	
	B.3.3.2, B.6.3, B.6.4.4	
	B.3.3.1, B.6.4	
	B.6.4.2	
	B.3.3.2	
	B.3.3.2	
	B.1.2	
	B.3.4	
	B.3.1	
	A.1, A.2, A.4, A.5	
	B.8, B.8.4	
	B.8, B.8.7,	
	B.7.2, B.8.7 (t)	

Bibliography

Medical devices — Risk analysis.

4971, *Medical devices — Application of risk management to medical devices (ISO 14971:2000).*