SLOVENSKI STANDARD

SIST EN 376:2002

01-november-2002

Nadomeġļa:

SIST EN 376:2000

Informacije proizvajalca o diagnostiļnih reagentih in vitro za samopreskuġanje

Information supplied by the manufacturer with in vitro diagnostic reagents for self-testing

Bereitstellung von Informationen durch den Hersteller von Reagenzien für in-vitro-diagnostische Untersuchungen zur Eigenanwendung

Informations fournies par le fabricant de réactifs pour le diagnostic in vitro pour l'utilisation comme auto-test

Ta slovenski standard je istoveten z: EN 376:2002

ICS:

11.100.10	Diagnostiļni preskusni sistemi in vitro	In vitro diagnostic test systems

SIST EN 376:2002 **en**

EUROPEAN STANDARD

NORME EUROPÉENNE

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EN 376

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ICS 11.100

Supersedes EN 376:1992

English version

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This European Standard was approved by CEN on 20 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
EUROPÄISCHES KOMITEE FÜR NORMUNG

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

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Foreword

This European Standard 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 August 2002, and conflicting national standards shall be withdrawn at the latest by August 2002.

This European Standard supersedes EN 376:1992.

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 EU Directive(s).

For relationship with EU Directive(s), see informative annex ZA, which is an integral part of this standard.

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 the requirements for the information supplied by the manufacturer of in vitro diagnostic reagents for use in self-testing including reagent products, calibrators, control materials and kits, which hereafter are called IVD reagents.

NOTE This standard can also be applied to accessories.

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 editions of the publication referred to applies (including amendments).

ISO 1000, *SI units and recommendations for the use of their multiples and of certain other units.*

3 Terms and definitions

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

3.1
active ingredient
constituent that participates in the reaction used to measure or detect the analyte [EN 375:2001]

3.2
batch
lot
defined amount of material, either starting material, intermediate or finished product which is uniform in its properties and has been produced in one process or series of processes [EN 375:2001]

3.3
batch code
lot number
code that is a distinctive combination of numbers and/or letters which specifically identifies a batch and permits its manufacturing history to be traced [EN 375:2001]

3.4
calibrator
substance, material or article intended by its manufacturer to be used to establish the measurement relationships of an in vitro diagnostic medical device [EN 375:2001]

3.5
control material
substance, material or article intended by its manufacturer to be used to verify the performance characteristics of an in vitro diagnostic medical device [EN 375:2001]

3.6
expiry date
date up to which product performance is assured by the manufacturer based on the stability of the IVD reagent [EN 375:2001]

3.7
immediate container
primary container
packaging which protects the contents from contamination and/or other effects of the external environment [EN 375:2001]

NOTE Examples are a sealed vial, ampoule or bottle, a foiled pouch, or a sealed plastics bag containing e. g. test strips.

3.8
in vitro diagnostic reagent
IVD reagent
in vitro diagnostic medical device which is a reagent, reagent product, calibrator, control material or kit

NOTE 1 For the definition of an in vitro diagnostic medical device see [4].

NOTE 2 In some cases a particular IVD reagent, as defined for use in human medicine, may serve also in veterinary medicine.

[EN 375:2001]

3.9
instructions for use
information supplied by the manufacturer with an IVD reagent concerning the safe and proper use of the IVD reagent

3.10
kit
set of components (reagents and/or other materials) packaged together [EN 375:2001]

3.11
kit component
in vitro diagnostic medical device intended to be part of a kit [EN 375:2001]

NOTE Typical kit components are e. g. reagent carriers, calibrators or control materials.

3.12
label
printed, written or graphic information placed on a container [EN 375:2001]

3.13
lay person
individual who does not have specific medical education

3.14
outer container
sales packaging
material used in the packaging of the immediate container(s) of (an) IVD reagent(s) consisting of a single entity or an assembly of different or identical components [EN 375:2001]

3.15
reagent product
reagent carrier
product in which the reagents are fixed to or included in a carrier [EN 375:2001]

EXAMPLES Test strips, slides, test plates, test sticks.

3.16
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

3.17
shelf life
period until expiry date [EN 375:2001]

3.18
specimen
biological material which is obtained in order to detect or to measure one or more quantities [EN 375:2001]

3.19
stability
ability of an IVD reagent, when kept under specified conditions, to retain throughout the shelf-life its properties and/or performance within limits specified by the manufacturer [EN 375:2001]

4 Requirements for labels

4.1 Outer container

4.1.1 General

The label for an outer container shall give the information specified in 4.1.2 to 4.1.10.

A statement that the instructions for use are to be read carefully shall be made on the outer container or, if space does not permit, in the instructions for use.

The language(s) used shall be (an) official Community language(s), legally acceptable in the country in which the IVD reagent is distributed; additional languages are optional, bearing in mind the needs of the anticipated users. Information which is a proper name, address, or symbol does not require to be expressed in multiple languages.

4.1.2 Manufacturer

The name and address of the manufacturer shall be given.

NOTE The manufacturer is the entity which has taken legal responsibility for the IVD reagent.

The name and address of the authorized representative shall also be given when this is a legal requirement.

4.1.3 Product name

The product name shall be given.

When the name does not uniquely identify the product, an additional means of identification shall be given.

4.1.4 Microbiological state

If necessary for proper performance of the reagent, the microbiological state or state of cleanliness, e. g. "microbiologically controlled" or "sterile", shall be given.

4.1.5 Batch code

A batch code shall be given.

If a kit contains different components bearing different batch codes, the batch code given on the outer container shall enable the product history to be traced from the manufacturer's production files.

NOTE The graphical symbol as given in EN 980 should be used.

4.1.6 Expiry date

An expiry date based upon the stated storage instructions shall be given. This shall be expressed as the year, the month, and, where relevant, the day, in that order. In the case of year and month this means that the expiry date is the last day of the month indicated. The label of the outer container shall give the expiry date of the component having the earliest expiry date or an earlier date, if appropriate.

NOTE 1 The graphical symbol as given in EN 980 should be used.

NOTE 2 The format for the expiry date should be either "CCYY-MM-DD" or "CCYY-MM".

4.1.7 Contents

The number of measurements or tests that can be performed shall be stated.

In the case of a kit the components shall be identified in the same way as on the label of the immediate containers as specified in 4.2.3.

4.1.8 Intended purpose

A brief indication, e. g. "pregnancy test", plus a statement in lay terms clearly signifying in vitro use, e. g. "not to be swallowed", shall be given. The fact that the IVD reagent is intended for self-testing shall be clearly stated.

NOTE A graphical symbol for in vitro diagnostic medical device should be used.[1)]

4.1.9 Storage and handling information

The storage conditions necessary to assure the stability of the product in the unopened state shall be indicated. Recommended storage temperature intervals shall be given.

EXAMPLES:

2 °C to 8 °C	or	2...8 °C	or	graphical symbol according to ISO 7000-0632
-18 °C or below	or	≤ -18 °C	or	graphical symbol according to ISO 7000-0533

Other conditions that affect stability (e. g. light or humidity) shall be mentioned.

Any other particular measures to be taken in the handling of the product shall be given (e. g. "treat as fragile").

4.1.10 Warnings and precautions

If an IVD reagent is considered dangerous (e. g. chemical or biological risk), the outer container shall be labelled with the appropriate danger symbol(s). In the case of chemical hazards, if the IVD reagent is not accompanied by instructions for use giving appropriate risk and safety phrases, these phrases shall be given on the label of the outer container.

NOTE For chemical hazards labelling see [3].

[1)] Graphical symbol as given in ISO 15223/DAM 1:1999 and as proposed for a future revision of EN 980.