National Standards Authority of Ireland

IRISH STANDARD

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INSTRUCTIONS FOR USE FOR IN VITRO DIAGNOSTIC INSTRUMENTS FOR SELF-TESTING

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EUROPEAN STANDARD
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Supersedes EN 592:1994

English version

Instructions for use for in vitro diagnostic instruments for self-testing

Instructions d'utilisation d'instruments pour le diagnostic in vitro pour usage comme auto-test

Gebrauchsanweisungen für Geräte für in-vitro-diagnostische Untersuchungen zur Eigenanwendung

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
EUROPAISCHES KOMITEE FUR NORMUNG

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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of an identical text or by endorsement, at the latest by August 2002, and conflicting national standards shall be withdrawn at the latest by August 2002.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 592:1994.

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 contents of instructions for use for in vitro diagnostic instruments including apparatus and equipment for self-testing which hereafter are called IVD instruments.

NOTE 1 Instructions for use are essential to enable the safe and proper operation of IVD instruments by lay persons.

NOTE 2 This standard can also be applied to accessories.

This standard is not applicable to field repair instructions.

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
in vitro diagnostic instrument
IVD instrument
in vitro diagnostic medical device which is an instrument, apparatus or equipment

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

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

[EN 591:2001]

3.2
instructions for use
information supplied by the manufacturer with an IVD instrument concerning the proper use and the safe and correct operation, maintenance and basic trouble-shooting of the IVD instrument [EN 591:2001]

3.3
lay person
individual who does not have specific medical education [EN 376:2002]

3.4
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]

3.5
specimen
biological material which is obtained in order to detect or to measure one or more quantities [EN 375:2001]

4 Form and presentation of the instructions for use

The wording shall be readily understood. Consideration shall be given to the following aspects of presentation, where appropriate:

a) overview of operating elements;

b) flow and block diagrams;

c) integration and arrangement of text/illustrations;

d) graphic emphasis of warnings;

e) examples;

f) diagrams of procedural steps.

5 Requirements for the content of the instructions for use

5.1 General

Instructions for use for IVD instruments shall contain the information given in 5.2 to 5.19. The information provided shall be easy to read and well-organized. The print shall be easily legible and terms simple and not unnecessarily technical or scientific. Symbols and illustrations shall be used wherever possible. A statement that the instructions for use are to be read carefully shall be made.

Where appropriate, instructions for use shall include a table of contents and an index.

The language(s) used shall be (an) official Community language(s), legally acceptable in the country in which

the IVD instrument is distributed; additional languages are optional, bearing in mind the needs of the anticipated users.

5.2 Graphical symbols

Any graphical symbols used on the IVD instrument shall be explained in the instructions for use. There are, however, certain well-understood symbols already in use which are recognised to be suitable without need for further explanation, i. e. those symbols as so identified in EN 980.

5.3 Manufacturer

The name and address of the manufacturer shall be given.

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

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

5.4 Identification

The name of the IVD instrument and/or separate instrument components shall be provided.

5.5 Storage and handling

Instructions relevant to any particular storage and/or handling conditions shall be given.

5.6 Warnings and precautions

Any warnings and precautions relevant to any special, unusual risks related to installation, operation, maintenance, transportation, storage or disposal of the IVD instrument shall be given.

5.7 Intended purpose

The intended purpose of the IVD instrument and the fact that it is intended for self-testing shall be clearly stated.

5.8 Installation

5.8.1 General

Where appropriate, instructions for setting up the IVD instrument shall be given.

5.8.2 Action upon delivery

Where appropriate, information shall be provided on the following:

a) unpacking;

b) checking delivery for completeness;

c) checking for damage during transport.