National Standards Authority of Ireland

IRISH STANDARD

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INFORMATION SUPPLIED BY THE MANUFACTURE WITH IN VITRO DIAGNOSTIC REAGENTS FOR SELF-TESTING

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English version

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

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

Bereitstellung von Informationen durch den Hersteller von Reagenzien 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
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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of an identical text or by endorsement, at the latest by August 2002, and conflicting national standards shall be withdrawn at the latest by August 2002.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]