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IRISH STANDARD

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IN VITRO DIAGNOSTIC MEDICAL DEVICES - INFORMATION SUPPLIED BY THE MANUFACTURER WITH IN VITRO DIAGNOSTIC REAGENTS FOR STAINING IN BIOLOGY

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English version

In vitro diagnostic medical devices - Information supplied by the manufacturer with in vitro diagnostic reagents for staining in biology

Dispositifs médicaux de diagnostic in vitro - Informations fournies par le fabricant de réactifs de coloration de diagnostic in vitro utilisés en biologie

In-vitro-Diagnostika - Bereitstellung von Informationen durch den Hersteller von in-vitro-diagnostischen Reagenzien für biologische Färbungen

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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.

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of an identical text or by endorsement, at the latest by July 1999, and conflicting national standards shall be withdrawn at the latest by July 1999.

Annexes A and B are given for information.

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, Netherlands, Norway, Portugal, Spain, Sweden, Switzerland and the United Kingdom.

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Introduction

This European Standard relates to EN 375, *In vitro diagnostic systems - Requirements for labelling of in vitro diagnostic reagents for professional use* and EN 376, *In vitro diagnostic systems - Requirements for labelling of in vitro diagnostic reagents for self testing* and should be used in conjunction with these.

The use of reagents required for staining in biology as well as the specific examples of information supplied by the manufacturer for four staining procedures as provided in Annex A are based on a European consensus; they constitute the scientific justification for the requirements listed in clause 4. This information is to assist manufacturers, suppliers, and vendors of dyes, stains, chromogenic reagents, and other reagents used for staining in biology in complying with the required specific product data.

1 Scope

This European standard specifies requirements for information supplied by the manufacturer with reagents used in staining in biology. It applies to producers, suppliers, and vendors of dyes, stains, chromogenic reagents, and other reagents used for staining in biology. The requirements for information supplied by the manufacturer specified in this European standard are a prerequisite for achieving comparable and reproducible results in all fields of staining in biology.

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.

EN 375	In vitro diagnostic systems - Requirements for labelling of in vitro diagnostic reagents for professional use
EN 376	In vitro diagnostic systems - Requirements for labelling of in vitro diagnostic reagents for self testing
ISO 31-8	Quantities and units - Part 8: Physical chemistry and molecular physics
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
information supplied by the manufacturer
All printed, written, graphic or other information affixed to, or accompanying an in vitro diagnostic reagent.

3.2
label
Any printed, written or graphic information placed on a container. [EN 375]

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