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

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EESTI STANDARDI EESSÕNA

NATIONAL FOREWORD

Käesolev Eesti standard EVS-EN 12376:2001 sisaldab Euroopa standardi EN 12376:1999 ingliskeelset teksti. Käesolev dokument on jõustatud 18.06.2001 ja selle kohta on avaldatud teade Eesti standardiorganisatsiooni ametlikus väljaandes. Standard on kättesaadav Eesti standardiorganisatsioonist.	This Estonian standard EVS-EN 12376:2001 consists of the English text of the European standard EN 12376:1999. This document is endorsed on 18.06.2001 with the notification being published in the official publication of the Estonian national standardisation organisation. The standard is available from Estonian standardisation organisation.

Käsitlusala: This standard specifies requirements for information supplied by the manufacturer with reagents used in staining in biology.	**Scope:** This standard specifies requirements for information supplied by the manufacturer with reagents used in staining in biology.

ICS 11.100

Võtmesõnad: biology, chemical reagents, coloration, definitions, information, in-vitro diagnostic, labelling, medicine

EUROPEAN STANDARD
NORME EUROPÉENNE
EUROPÄISCHE NORM

EN 12376

January 1999

ICS 11.100

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

This European Standard was approved by CEN on 1998-08-27.

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 Central Secretariat or to any CEN member.

The European Standards exist 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 Central Secretariat has the same status as the official versions.

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CEN

European Committee for Standardization
Comité Européen de Normalisation
Europäisches Komitee für Normung

Central Secretariat: 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.

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.

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]