SLOVENSKI STANDARD
SIST EN ISO 19001:2013

01-junij-2013

Nadomešča:
SIST EN 12376:2000

Diagnostični preskusni sistemi in vitro - Informacije, ki jih priskrbi proizvajalec diagnostičnih reagentov za barvanje in vitro v biologiji (ISO 19001:2013)

In vitro diagnostic medical devices - Information supplied by the manufacturer with in vitro diagnostic reagents for staining in biology (ISO 19001:2013)

In-vitro-Diagnostika - Bereitstellung von Informationen durch den Hersteller von in-vitro-diagnostischen Reagenzien für biologische Färbungen (ISO 19001:2013)

Dispositifs médicaux de diagnostic in vitro - Informations fournies par le fabricant avec les réactifs de coloration de diagnostic in vitro utilisés en biologie (ISO 19001:2013)

Ta slovenski standard je istoveten z: **EN ISO 19001:2013**

ICS:

11.100.10	Diagnostični preskusni sistemi in vitro	In vitro diagnostic test systems

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EUROPEAN STANDARD

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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 (ISO 19001:2013)

Dispositifs médicaux de diagnostic in vitro - Informations fournies par le fabricant avec les réactifs de coloration de diagnostic in vitro utilisés en biologie (ISO 19001:2013)

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This European Standard was approved by CEN on 14 March 2013.

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EUROPEAN COMMITTEE FOR STANDARDIZATION
COMITÉ EUROPÉEN DE NORMALISATION
EUROPÄISCHES KOMITEE FÜR NORMUNG

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Foreword

This document (EN ISO 19001:2013) has been prepared by Technical Committee ISO/TC 212 "Clinical laboratory testing and in vitro diagnostic test systems" in collaboration with 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of an identical text or by endorsement, at the latest by September 2013, and conflicting national standards shall be withdrawn at the latest by March 2016.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. CEN [and/or CENELEC] shall not be held responsible for identifying any or all such patent rights.

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The text of ISO 19001:2013 has been approved by CEN as EN ISO 19001:2013 without any modification.

INTERNATIONAL STANDARD

ISO 19001

Second edition
2013-03-15

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 avec les réactifs de coloration de diagnostic in vitro utilisés en biologie

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Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 2.

The main task of technical committees is to prepare International Standards. Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

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ISO 19001 was prepared by Technical Committee ISO/TC 212, *Clinical laboratory testing and in vitro diagnostic test systems*.

This second edition cancels and replaces the first edition (ISO 19001:2002), which has been technically revised.

Introduction

This International Standard relates to ISO 18113-1 and ISO 18113-2, which can be used in conjunction with it.

The use of reagents required for staining in biology as well as the specific examples of information supplied by the manufacturer for two 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 intended 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.