DRAFT INTERNATIONAL STANDARD ISO/DIS 18113-4

ISO/TC **212** Secretariat: **ANSI**

Voting begins on: **2006-11-30** Voting terminates on: **2007-04-30**

INTERNATIONAL ORGANIZATION FOR STANDARDIZATION • МЕЖДУНАРОДНАЯ ОРГАНИЗАЦИЯ ПО СТАНДАРТИЗАЦИИ • ORGANISATION INTERNATIONALE DE NORMALISATION

Clinical laboratory testing and in vitro diagnostic medical systems — Information supplied by the manufacturer (labelling) —

Part 4:
In vitro diagnostic reagents for self-testing

Essais cliniques de laboratoire et systèmes médicaux de diagnostic in vitro — Informations fournies par le fabricant (marquage) —

Partie 4: Réactifs de diagnostic in vitro pour auto-essais

ICS 11.100.10

ISO/CEN PARALLEL ENQUIRY

The CEN Secretary-General has advised the ISO Secretary-General that this ISO/DIS covers a subject of interest to European standardization. **In accordance with the ISO-lead mode of collaboration as defined in the Vienna Agreement, consultation on this ISO/DIS has the same effect for CEN members as would a CEN enquiry on a draft European Standard.** Should this draft be accepted, a final draft, established on the basis of comments received, will be submitted to a parallel two-month FDIS vote in ISO and formal vote in CEN.

In accordance with the provisions of Council Resolution 15/1993 this document is circulated in the English language only.

Conformément aux dispositions de la Résolution du Conseil 15/1993, ce document est distribué en version anglaise seulement.

To expedite distribution, this document is circulated as received from the committee secretariat. ISO Central Secretariat work of editing and text composition will be undertaken at publication stage.

Pour accélérer la distribution, le présent document est distribué tel qu'il est parvenu du secrétariat du comité. Le travail de rédaction et de composition de texte sera effectué au Secrétariat central de l'ISO au stade de publication.

Contents

Page

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.

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

ISO 18113-4 was prepared by Technical Committee ISO/TC 212, *Clinical laboratory testing and in vitro diagnostic test systems*.

ISO 18113 consists of the following parts, under the general title *Clinical laboratory testing and* in vitro *diagnostic test systems* — In vitro *diagnostic medical devices* — *Information supplied by the manufacturer (labelling)*:

— *Part 1: Vocabulary and general requirements;*

— *Part 2:* In vitro *diagnostic reagents for professional use;*

— *Part 3:* In vitro *diagnostic instruments for professional use;*

— *Part 4:* In vitro *diagnostic reagents for self-testing;*

— *Part 5:* In vitro *diagnostic instruments for self-testing*.

This is the first edition.

Introduction

Manufacturers of *in vitro* diagnostic (IVD) reagents for self-testing supply users with information to enable their safe use and expected performance. The type and level of detail varies according to the intended uses and country-specific regulations.

The Global Harmonization Task Force (GHTF) is encouraging the elimination of unnecessary differences among regulatory jurisdictions in order to reduce the time required for regulatory compliance and allows patients earlier access to new technologies and treatments. [9] This International Standard provides a basis for harmonization of labelling requirements for IVD reagents for self-testing.

This part of ISO 18113 is concerned solely with information supplied with IVD reagents, calibrators and control materials intended for self-testing. It is intended to be used in conjunction with 18113-1, which contains the general requirements for information supplied by the manufacturer and definitions of general labelling concepts.

This part of ISO 18113 is based on EN 376:2002*, Information supplied by the manufacturer with* in vitro *diagnostic reagents for self-testing*. [5] The text has been modified to conform to Part 2 of the ISO/IEC Directives [4], but the requirements including those in ISO 18113-1 are substantially equivalent to the original European harmonized standard. This International Standard is intended to support the essential labelling requirements of all the GHTF partners, as well as other countries that have enacted or plan to enact labelling regulations for IVD medical devices.

For IVD reagents, calibrators and/or control materials that are intended to be used as a system with an instrument provided by the same manufacturer, this part of ISO 18113 is also intended to be used together with ISO 18113-5 [2].

Clinical laboratory testing and in vitro diagnostic medical systems — Information supplied by the manufacturer (labelling) —

Part 4:

In vitro diagnostic reagents for self-testing

1 Scope

This part of ISO 18113 specifies requirements for information supplied by the manufacturer of IVD reagents for self-testing.

Furthermore, this part of ISO 18113 applies to information supplied by the manufacturer with calibrators and control materials intended for use with IVD medical devices for self-testing.

This part of ISO 18113 can also be applied to accessories, where appropriate.

This part of ISO 18113 applies to labels for the outer and immediate container and to the instructions for use.

This part of ISO does not apply to

a) material safety data sheets,

b) information supplied with reagents for performance evaluation (e.g., for investigational use only),

c) IVD instruments or equipment, or

d) IVD reagents for professional use.

2 Normative references

The following referenced documents are indispensable for the application of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

EN 980, *Graphical symbols for use in the labelling of medical devices*

ISO 8601, *Data elements and interchange formats — Information interchange — Representation of dates and times*

ISO 14971, *Application of risk management to medical devices*

ISO 15198, *Clinical laboratory medicine* — In vitro *diagnostic medical devices — Validation of user quality control procedures by the manufacturer*

ISO 15223, *Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied*

ISO 18113-1, *Clinical laboratory testing and* in vitro *diagnostic test systems* — In vitro *diagnostic medical devices — Information supplied by the manufacturer (labelling) — Part 1: General requirements and definitions*

3 Terms and definitions

For the purposes of this document, the concepts and definitions given in ISO 18113-1 apply.

4 General

4.1 Essential requirements

The requirements of ISO 18113-1 apply.

ISO standards for specific IVD medical devices may also contain requirements for information supplied by the manufacturer.

EXAMPLES ISO 15197, for *in vitro* monitoring systems intended for self-testing of blood-glucose in managing diabetes mellitus; ISO 17593, for *in vitro* monitoring systems intended for self-testing of anticoagulant therapy

4.2 Identification of kit components

In the case of a kit, each component shall be identified by name, letter, number, symbol, colour or graphics in the same manner on all labels and the instructions for use.

4.3 Form and presentation of the instructions for use

4.3.1 The instructions for use shall be written to be easily understood and applied by a lay person.

4.3.2 The information supplied shall be sufficient to enable a lay person to use the IVD reagent safely and properly and to understand the IVD examination results.

NOTE Recommendations for developing user instruction manuals for medical devices used in home health care may be found in reference [10].

5 Content of the outer container label

5.1 Manufacturer

The name and location of the manufacturer shall be given.

The location should include city, state, country, province and region, where appropriate.

NOTE In the European Union, the name of the manufacturer's authorized representative is required on the outer container label or in the instructions for use if the legal manufacturer is not located within the EU. See reference [8].

5.2 Identification of the IVD reagent

5.2.1 IVD reagent name

The name of the IVD reagent shall be given.

When the name does not uniquely identify the IVD reagent, an additional means of identification shall also be given.

EXAMPLE catalogue number, commodity number

5.2.2 Batch code

A batch code shall be given.

If a kit contains different components bearing different batch codes, the batch code indicated on the outer container shall enable the individual batch code of each component to be traced from the manufacturer's production record.

5.3 Contents

The mass, volume and/or the number of examinations shall be indicated, where appropriate.

5.4 Intended use

If the intended use is not indicated by the name of the IVD reagent, then an abbreviated intended use statement shall be given in terminology suitable for a lay person.

EXAMPLE pregnancy test

The fact that the IVD reagent is intended for self-testing shall be clearly stated.

5.5 *In vitro* diagnostic use

The *in vitro* diagnostic use of the reagent shall be stated, in suitable terminology for a lay person.

EXAMPLE For use outside the body.

5.6 Storage and handling conditions

The storage conditions necessary to maintain the stability of the reagents, calibrators and control materials in the unopened state shall be indicated.

EXAMPLES 2 to 8 °C or 2…8 °C or graphical symbol

-18 °C or below or graphical symbol

Other conditions that affect stability of the reagents, calibrators and control materials shall be indicated.

EXAMPLES light, humidity

Any other conditions that affect the handling or storage of the reagents, calibrators and control materials shall be specified.

EXAMPLE fragile

5.7 Expiry date

An expiry date based upon the stated storage instructions shall be indicated.

Expiry dates shall be expressed in a format generally familar to the lay users.

EXAMPLES 2006-Jan-01 or Jan 01, 2006