SLOVENSKI STANDARD
SIST EN 592:2000

01-januar-2000

Diagnostiļ ni sistemi in vitro - Zahteve za priroļ nike za uporabnike diagnostiļ nih instrumentov in vitro na domu

In vitro diagnostic systems - Requirements for user manuals for in vitro diagnostic instruments for home use

In-vitro-Diagnostik/Diagnostika - Anforderungen an Benutzerhandbücher für In-vitro-Diagnostika-Geräte zum Gebrauch zu Hause

Systemes d'analyses médicales in vitro - Regles pour les manuels d'utilisation d'instruments pour le diagnostic in vitro pour usage a domicile

Ta slovenski standard je istoveten z: **EN 592:1994**

ICS:

11.100.10	Diagnostiļ ni preskusni sistemi in vitro	In vitro diagnostic test systems

SIST EN 592:2000 **en**

EUROPEAN STANDARD **EN 592**

NORME EUROPÉENNE

EUROPÄISCHE NORM September 1994

UDC 616-07:579.61:658.62.04.11

Descriptors: medicine, diagnosis, medical equipment, utilization, handbooks, specifications

English version

In vitro diagnostic systems - Requirements for user manual for in vitro diagnostic instruments for home use

Systèmes d'analyses médicales in vitro - Règles pour le manuel d'utilisation d'instruments pour le diagnostic in vitro pour usage à domicile

In-vitro-Diagnostik/Diagnostika - Anforderungen an Benutzerhandbücher für In-vitro-Diagnostica-Geräte zum Gebrauch zuHause

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CEN

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

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Foreword

This European Standard has been prepared by the Technical Committee CEN/TC 140 "In vitro diagnostic systems", the secretariat of which is held by DIN.

Annexes designated "informative" are given only for information. In this standard annex A is informative.

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of an identical text or by endorsement, at the latest by March 1995, and conflicting national standards shall be withdrawn at the latest by March 1995.

According to the CEN/CENELEC Internal Regulations, the following countries are bound to implement this European Standard: Austria, Belgium, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Luxembourg, Netherlands, Norway, Portugal, Spain, Sweden, Switzerland, United Kingdom.

1 Scope

This standard specifies the content of user manuals for in vitro diagnostic instruments for home use.

NOTE: User manuals are essential to enable the safe and proper operation of instruments by trained and untrained personnel.

This standard is not applicable to field repair instructions.

2 Definitions

For the purposes of this standard, the following definitions apply:

2.1 Calibration[1]): The set of operations that establish, under specified conditions, the relationship between values indicated by a measuring instrument or measuring system, or values represented by a material measure or a reference material, and the corresponding values of a measurable quantity realized by a measurement standard.

2.2 Calibrator[1]): Reference material used for calibration.

2.3 In vitro diagnostic instrument[1]): Any instrument which, used alone or in combination with other in vitro diagnostic medical devices, is intended by the manufacturer wholly or mainly to be used in vitro for the examination of substances derived from the human body for the purpose of providing information relevant to the detection, diagnosis, monitoring or treatment of physiological states, states of health or disease, or congenital abnormality.

NOTE: A given in vitro diagnostic instrument, as defined for use in human medicine, in some cases may serve also in veterinary medicine.

2.4 In vitro diagnostic system[1]): Any measuring system which is intended by the manufacturer wholly or mainly to be used in vitro for the examination of substances derived from the human body for the purpose of providing information relevant to the detection, diagnosis, monitoring or treatment of physiological states, states of health or disease, or congenital abnormality.

NOTE: A given in vitro diagnostic system, as defined for use in human medicine, in some cases may serve also in veterinary medicine.

2.5 Manufacturer[1]): The natural or legal person with responsibility for the design, manufacture, packaging and labelling of a device before it is placed on the market under his own name, regardless of whether these operations are carried out by that person himself or on his behalf by a third party.

2.6 Manufacturing[1]): The complete process of production from the acquisition of all materials through all processing stages and including final packaging.

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[1]) Provisional statement, subject to revision depending upon future EC Directives and/or European Standards.

2.7 Specimen[1]): Biological material which is obtained in order to detect or to measure one or several quantities.

2.8 User manual[1]): Document accompanying an instrument containing information for the safe and correct operation, maintenance and basic trouble-shooting of the instrument.

3 Form and presentation of the user manual

The wording should be readily understood. Consideration should be given to the following aspects of presentation:

a) naming of operating elements (overview);
b) flow and block diagrams;
c) integration and arrangement of text/illustrations;
d) graphic emphasis of warnings;
e) examples;
f) diagrams of essential manipulations.

4 Content of the user manual

4.1 General

User manuals for in vitro diagnostic instruments shall contain the information given in 4.2 to 4.13.

The language(s) of the country in which the product is distributed shall be used.

NOTE: Multilingual user manuals are recommended.

4.2 Identification

The following information shall be provided:

a) name of the instrument and/or instrument modules;
b) name of manufacturer;
c) date of issue or of revision;
d) table of contents, index.

4.3 Precautionary measures and warnings

Any warnings shall be given in the appropriate sections of the user manual relevant to:

a) possible hazards during installation, operation, maintenance, transportation and storage;
b) interferences and actions not recommended by the manufacturer.

4.4 Symbols

An explanation of symbols used on the instrument shall be given.

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[1]) see page 3

4.5 Installation

4.5.1 General

Instructions for setting up the instrument shall be given.

4.5.2 Action upon delivery

Information shall be provided on the following:

a) storage;
b) unpacking;
c) checking delivery for completeness;
d) checking for damage during transport.

4.5.3 Preparation prior to installation

Information shall be provided on the following:

a) installation site requirements;
b) technical prerequisites.

4.5.4 Bringing into operation

Information shall be provided on the following:

a) set up;
b) introduction, brief description;
c) checks.

4.6 Checks

Information shall be provided on the following:

a) automatic checks on the system;
b) specific performance checks.

4.7 Theory

Short summary of basic theory as far as necessary for comprehension of the instrument operation by the lay user shall be given.

4.8 Performance criteria and limitations

Information shall be provided on the following:

a) general statements;
b) reliability of the instrument and the limitation of use.

NOTE: This information should be expressed and presented in layman's terms.

4.9 Operating procedure

4.9.1 General

Where appropriate, operating procedures shall be augmented by

a) line drawings;
b) photographs.

NOTE: It is strongly recommended that the operating procedure should be easy to understand.

4.9.2 Operation

Information shall be provided on the following:

a) switching on;
b) placing on stand-by;
c) switching off;
d) taking out of operation.

4.9.3 Performance check

Information shall be provided on the following:

a) controls;
b) checking the instrument;
c) some form of simple performance checks of the entire system.

4.9.4 Special functions

Information shall be provided on special functions where applicable.

NOTE: Examples include information on the following:

a) specimen identification;
b) data output, notation, storage, security and transfer.

4.9.5 Disposal instructions

Where appropriate, information shall be provided on the disposal of materials.

NOTE: Examples include disposal of the following items:

a) consumables;
b) reagents including mixtures with specimens;
c) instruments or components thereof.

4.10 Maintenance

Simple maintenance instructions shall be provided on the following:

a) preventive maintenance;
b) cleaning instructions;
c) disinfection, sterilization;
d) components list including relevant working materials, tools;
e) consumables.

4.11 Trouble-shooting

Information shall be provided on the following:

a) messages, error signals;
b) error searching;
c) correction and elimination of error by the user;
d) errors necessitating service calls.

4.12 Follow-up action

Specific information as to follow-up action shall be given.

NOTE: For example "Consult your physician".

4.13 Technical specifications

Information shall be provided on the following:

a) physical environment (e.g. humidity, temperature);
b) dimensions, mass;
c) basic settings made by the manufacturer;
d) physical data (e.g. voltage);
e) consumption values (e.g. electrical power, water).

5 Supplementary information

5.1 General

If appropriate, user manuals for in vitro diagnostic instruments shall provide the supplementary information given in 5.2 to 5.7.

5.2 List of uses and applications

Information shall be provided on the following:

a) index of methods;
b) reagents;
c) method sheets.