SLOVENSKI STANDARD
SIST EN 591:2000

01-januar-2000

Diagnostiļ ni sistemi in vitro - Zahteve za priroļ nike za uporabnike diagnostiļ nih instrumentov in vitro za profesionalno uporabo

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

In-vitro Diagnostik/Diagnostika - Anforderungen an Benutzerhandbücher für In-vitro-Diagnostika-Geräte zum Gebrauch durch Fachpersonal

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

Ta slovenski standard je istoveten z: **EN 591:1994**

ICS:

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

SIST EN 591:2000 **en**

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN 591

September 1994

UDC 616-07:579.61:658.62.004.11

Descriptors: medicine, diagnosis, medical equipment, utilization, handbook

English version

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

Systèmes d'analyses médicales in vitro - Règles pour les manuels d'utilisation d'instruments pour le diagnostic in vitro pour usage professionnel

In-vitro-Diagnostik/Diagnostika - Anforderungen an Benutzerhandbücher für In-vitro-Diagnostika-Geräte zum Gebrauch durch Fachpersonal

This European Standard was approved by CEN on 1994-09-06. 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.

CEN members are the national standards bodies of Austria, Belgium, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Luxembourg, Netherlands, Norway, Portugal, Spain, Sweden, Switzerland and United Kingdom.

CEN

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

Central Secretariat: rue de Stassart,36 B-1050 Brussels

Ref. No. EN 591:1994 E

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 professional use.

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

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 Internal quality control[1]): Operational techniques and activities within a production site that are used to fulfil requirements for quality of services.

NOTE: Internal quality control comprises all steps of activity for production of results from assessing clinical needs, via collection of sample, and measurement of a measurable quantity to reporting of result of measurement.

2.4 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.

2.5 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.

---

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

2.6 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.

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

2.8 Professional use[1]): Use by personnel who have received special education and training with regard to laboratory procedures utilizing in vitro diagnostic systems.

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

2.10 Supplier[1]): The party that is responsible for the product, process or service.

NOTE: The definition may apply to manufacturers, distributors, importers, assemblers, service organizations, etc.

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

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 4.12.

Languages shall be used in accordance with the requirements of the country(ies) in which the product is distributed.

NOTE: Multilingual user manuals are recommended.

---

[1]) See page 3

4.2 Identification

The following information shall be provided:

a) name of the instrument and/or instrument modules, including, where applicable, software;
b) name of manufacturer;
c) date of issue or 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.

4.5 Installation

4.5.1 General

Instructions for setting up the instrument shall be given when the installation can be carried out by the user.

NOTE: These instructions are not necessary when the installation is carried out exclusively by personnel from the supplier.

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 (e.g. load bearing capacity).

4.5.4 Bringing into operation:

Information shall be provided on the following:

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

4.6 Theory

Basic theory of the instrument operation shall be given.

4.7 Functions

Information shall be provided on the following:

a) description, purpose;
b) principles of working;
c) operation;
d) specifications;
e) automatic checks on the system;
f) specific performance checks.

4.8 Performance criteria and limitations

Information shall be provided on the following:

a) general statements;
b) performance characteristics (e.g. accuracy, imprecision, linearity, throughput).

4.9 Operating procedure

4.9.1 Preparation

Information shall be provided on the following:

a) checks;
b) calibration, adjustment;
c) specimen (type, handling);
d) reagent(s);
e) any special equipment required in order to use the instrument.

4.9.2 Measuring procedure

Information shall be provided on the following:

a) start up;
b) operational instructions.

4.9.3 Presentation of data

The following elements shall be included if appropriate:

a) reading of result(s);
b) calculation;
c) analytical interpretation.

4.9.4 Shut-down procedure

Information shall be provided on the following:

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

4.9.5 Emergency analyses

Operating procedure for emergency analyses shall be provided where applicable.

4.9.6 Internal quality control

Information shall be provided on the following:

a) checking the instrument;
b) validation of results;
c) internal quality control of the entire in vitro diagnostic system.

4.9.7 Special functions

Information shall be provided on special functions where applicable.

NOTE: Examples include information on the following:

a) special function and performance checks;
b) specimen identification;
c) data output, notation, storage, security and transfer;
d) special settings other than the normal mode of operation;
e) interface protocol.

4.9.8 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

Information shall be provided on the following:

a) preventive maintenance;
b) cleaning instructions;
c) disinfection, sterilisation;
d) components list, including relevant working materials, tools;
e) consumables;
f) servicing;
g) list of recommended spare parts.