



**SLOVENSKI STANDARD**  
**SIST EN 1658:2000**  
**01-januar-2000**

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Requirements for marking of in vitro diagnostic instruments

Anforderungen an die Kennzeichnung von In-vitro-Diagnostika-Geräten

Exigences de marquage des instruments de diagnostic in vitro

ITEH STANDARD PREVIEW  
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Ta slovenski standard je istoveten z: **EN 1658:1996**

SIST EN 1658:2000

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**ICS:**

11.100.10	Öäē } [ • cã } ä   ^ • \ • } ä • ä c { äē Aä [	In vitro diagnostic test systems
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**SIST EN 1658:2000** **en**

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EUROPEAN STANDARD

EN 1658

NORME EUROPÉENNE

EUROPÄISCHE NORM

December 1996

ICS 11.100

Descriptors: medicine, diagnosis, bioassay, medical equipment, marking, specifications

English version

## Requirements for marking of in vitro diagnostic instruments

Exigences de marquage des instruments de diagnostic in vitro      Anforderungen an die Kennzeichnung von In-vitro-Diagnostika-Geräten

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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.

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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

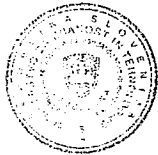
**Foreword**

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.

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of an identical text or by endorsement, at the latest by June 1997, and conflicting national standards shall be withdrawn at the latest by June 1997.

According to the CEN/CENELEC Internal Regulations, the national standards organizations of 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 and the United Kingdom.



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PREVIEWED BY ITCHEE FOR TECHNICAL

## 1 Scope

This standard provides requirements for the marking of in vitro diagnostic instruments. In connection with electrical equipment for laboratory use the requirements are additional to those specified in 5.1 to 5.3 of EN 61010-1 : 1993.

An easy to understand uniform marking of in vitro diagnostic instruments is important for their safe and correct handling.

## 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 980

Graphical symbols for use in the labelling of medical devices

EN 61010-1 : 1993

Safety requirements for electrical equipment for measurement, control and laboratory use – Part 1: General requirements (IEC 1010-1 : 1990 + A1 : 1992, modified)

## 3 Definitions

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

**3.1 in vitro diagnostic instrument<sup>1)</sup>**: 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 particular in vitro diagnostic instrument, as defined for use in human medicine, in some cases can serve also in veterinary medicine.

**3.2 marking<sup>1)</sup>**: An inscription, in writing or as a graphical symbol, permanently affixed to a product.

NOTE: Examples for inscriptions are manufacturer's or distributor's trademark, model or type number, identification of intended functions, supply voltage, particular warnings.

**3.3 permanently affixed<sup>1)</sup>**: Removable with a tool only or by appreciable force and able to withstand the effects of temperature, rubbing, solvents, reagents and vapours encountered during normal use.

## 4 Requirements for marking

### 4.1 General

5.1.1 of EN 61010-1 : 1993 applies with the following addition:

The markings shall not be on the bottom of the instrument, except when space is limited or on a hand-held instrument. Operating controls shall be marked with their function.

Graphical symbols shall be in accordance with EN 980.

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

NOTE: Multilingual markings are recommended.

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<sup>1)</sup> Provisional statement, subject to revision depending upon future EU Directives and/or European Standards

## 4.2 Identification

5.1.2 of EN 61010-1 : 1993 applies with the following addition:

- serial or lot number, and, if appropriate, date of manufacture (CCYY-MM-DD);
- name of the distributor if appropriate.

## 4.3 Mains supply

5.1.3 of EN 61010-1 : 1993 applies.

## 4.4 Fuses

5.1.4 of EN 61010-1 : 1993 applies.

## 4.5 Measuring circuit terminals

5.1.5 of EN 61010-1 : 1993 applies.

## 4.6 Terminals and operating devices

5.1.6 of EN 61010-1 : 1993 applies with the deletion of the following words in the first sentence:

"Where necessary for safety".

Add the following note to 5.1.6 f) of EN 61010-1 : 1993:

NOTE: In this context "device identification" is interpreted as "switch identification".

## 4.7 Instruments protected by double or reinforced insulation

5.1.7 of EN 61010-1 : 1993 applies with the following addition:

The marking shall be given on those parts of the equipment which cannot be removed by users.

## 4.8 Battery charging and battery compartments

4.8.1 5.1.8 of EN 61010-1 : 1993 applies with the following addition:

The marking shall be given on those parts of the equipment which cannot be removed by users.

4.8.2 The following information shall be marked in or near the battery compartment:

- the specific battery type;
- the polarity of the battery connections.

## 4.9 Warning markings

5.2 of EN 61010-1 : 1993 applies.

## 4.10 Durability of markings

5.3 of EN 61010-1 : 1993 applies with the following addition:

Markings shall be permanently affixed.

**Annex A (informative)**

**Bibliography**

IEC 27-1 : 1992 Letter symbols to be used in electrical technology – Part 1: General

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