BRITISH STANDARD

BS EN
1658 : 1997

Requirements for marking of in vitro diagnostic instruments

The European Standard EN 1658 : 1996 has the status of a British Standard

ICS 11.040.50; 11.100

Committees responsible for this British Standard

The preparation of this British Standard was entrusted to Technical Committee CH/69, In vitro diagnostic systems, upon which the following bodies were represented:

Association of Clinical Biochemists
Association of Clinical Pathologists
BLWA Ltd. The Association of the Laboratory Supply Industry
British Blood Transfusion Society
British In Vitro Diagnostics Association
British Society for Antimicrobial Chemotherapy
British Society for Haematology
Department of Health
Health and Safety Executive
Insitute of Biomedical Science
National Biological Standards Board
Public Health Laboratory Service
Royal College of Pathologists

This British Standard, having been prepared under the direction of the Health and Environment Sector Board, was published under the authority of the Standards Board and comes into effect on
15 May 1997

Amendments issued since publication

Amd. No.	Date	Text affected

The following BSI references relate to the work on this standard:
Committee reference CH/69
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Contents

National foreword

This British Standard has been prepared by Technical Committee CH/69, and is the English language version of EN 1658 : 1996 *Requirements for marking of in vitro diagnostic instruments*, published by the European Committee for Standardization (CEN).

Cross-references

Publication referred to	Corresponding British Standard
EN 980 : 1996	BS EN 980 : 1997 *Graphical symbols for use in the labelling of medical devices*
EN 61010-1 : 1993	BS EN 61010 *Safety requirements for electrical equipment for measurement, control and laboratory use* Part 1 : 1993 *General requirements*

Compliance with a British Standard does not of itself confer immunity from legal obligations.

Summary of pages

This document comprises a front cover, an inside front cover, pages i and ii, the EN title page, pages 2 to 4, an inside back cover and a back cover.

EUROPEAN STANDARD
NORME EUROPÉENNE
EUROPÄISCHE NORM

EN 1658

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

This European Standard was approved by CEN on 1996-12-06. 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.

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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

Ref. No. EN 1658 : 1996 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.

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.

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[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 particular in vitro diagnostic instrument, as defined for use in human medicine, in some cases can serve also in veterinary medicine.

3.2 marking[1)]

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[1)]

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.

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.

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

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*

List of references

See national foreword.

BS EN 1658 : 1997

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