National Standards Authority of Ireland

IRISH STANDARD

I.S. EN 1658:1997

ICS 11.100

REQUIREMENTS FOR MARKING OF IN VITRO DIAGNOSTIC INSTRUMENTS

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Údarás um Chaighdeáin Náisiúnta na hÉireann

DECLARATION

OF

SPECIFICATION

ENTITLED

REQUIREMENTS FOR MARKING OF IN VITRO DIAGNOSTIC INSTRUMENTS

AS

THE IRISH STANDARD SPECIFICATION FOR

REQUIREMENTS FOR MARKING OF IN VITRO DIAGNOSTIC INSTRUMENTS

NSAI in exercise of the power conferred by section 16 (3) of the National Standards Authority of Ireland Act, 1996 (No. 28 of 1996) and with the consent of the Minister for Enterprise, Trade and Employment, hereby declares as follows:

1. This instrument may be cited as the Standard Specification (Requirements for marking of in vitro diagnostic instruments) Declaration,1997.

2. (1) The Specification set forth in the schedule to this declaration is hereby declared to be the standard specification for Requirements for marking of in vitro diagnostic instruments. The Schedule comprises the text of EN 1658:1996.

(2) The said standard specification may be cited as Irish Standard EN 1658:1997 or as I.S. EN 1658:1997.

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

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.

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
Europaisches Komitee fur 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.