National Standards Authority of Ireland

IRISH STANDARD

I.S. EN 30993-6:1995

ICS 11.040.01

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BIOLOGICAL EVALUATION OF MEDICAL DEVICES. PART 6: TESTS FOR LOCAL EFFECTS AFTER IMPLANTATION (ISO 10993-6:1994)

This Irish Standard was published under the authority of the National Standards Authority of Ireland and comes into effect on: September 26, 1995

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Údarás um Chaighdeáin Náisiúnta na hÉireann

DECLARATION

OF

SPECIFICATION

ENTITLED

BIOLOGICAL EVALUATION OF MEDICAL DEVICES. PART 6: TESTS FOR LOCAL EFFECTS AFTER IMPLANTATION (ISO 10993-6:1994)

AS

THE IRISH STANDARD SPECIFICATION FOR

BIOLOGICAL EVALUATION OF MEDICAL DEVICES. PART 6: TESTS FOR LOCAL EFFECTS AFTER IMPLANTATION (ISO 10993-6:1994)

Forfás in exercise of the power conferred by section 20 (3) of the Industrial Research and Standards Act, 1961 (No. 20 of 1961) and the Industrial Development Act, 1993 (No. 19 of 1993), and with the consent of the Minister for Enterprise and Employment, hereby declares as follows:

1. This instrument may be cited as the Standard Specification (Biological Evaluation of Medical Devices. Part 6: Tests for Local Effects after Implantation (ISO 10993-6:1994)) Declaration, 1995.

2. (1) The Specification set forth in the Schedule to this declaration is hereby declared to be the standard specification for Biological Evaluation of Medical Devices. Part 6: Tests for Local Effects after Implantation (ISO 10993-6:1994). The Schedule comprises the text of EN 30993-6 : 1994.

(2) The said standard specification may be cited as Irish Standard/EN 30993-6:1995 or as I.S./EN 30993-6:1995.

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN 30993-6

October 1994

ICS 11.020

Descriptors: medical equipment, surgical equipment, surgical implants, dental equipment, dental materials, tests, biological tests, determination, acceptability

English version

Biological evaluation of medical devices - Part 6: Tests for local effects after implantation (ISO 10993-6:1994)

Evaluation biologique des dispositifs médicaux - Partie 6: Essais concernant les effets locaux après implantation (ISO 10993-6:1994)

Biologische Beurteilung von Medizinprodukten - Teil 6: Prüfungen auf lokale Effekte nach Implantation (ISO 10993-6:1994)

This European Standard was approved by CEN on 1994-10-19. 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

Foreword

This European Standard has been taken over by the Technical Committee CEN/TC 206 "Biocompatibilty of medical and dental materials and devices" from the work of ISO/TC 194 "Biological evaluation of medical devices" of the International Organization for Standardization (ISO).

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 April 1995, and conflicting national standards shall be withdrawn at the latest by April 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.

ISO 10 993 consists of the following parts, under the general title "*Biological evaluation of medical devices*":

Part 1:	Guidance on selection of tests
Part 2:	Animal welfare requirements
Part 3:	Tests for genotoxicity, carcinogenicity and reproductive toxicity
Part 4:	Selection of tests for interactions with blood
Part 5:	Tests for cytotoxicity: *in vitro* methods
Part 6:	Tests for local effects after implantation
Part 7:	Ethylene oxide sterilization residuals
Part 8:	Clinical investigation
Part 9:	Degradation of materials related to biological testing
Part 10:	Tests for irritation and sensitization
Part 11:	Tests for systemic toxicity
Part 12:	Sample preparation and reference materials

Future parts will deal with other relevant aspects of biological testing.

Annex A, B and C of this part of ISO 10 993 are for information only.

Endorsement notice

The text of the International Standard ISO 10993-6:1994 was approved by CEN as a European Standard without any modification.

NOTE: Normative references to international publications are listed in annex ZA (normative)