MALAYSIAN STANDARD

MS ISO 13779-4:2010

IMPLANTS FOR SURGERY - HYDROXYAPATITE - PART 4: DETERMINATION OF COATING ADHESION STRENGTH (ISO 13779-4:2002, IDT)

ISO 13779-4:2002 is endorsed as Malaysian Standard with the reference number MS ISO 13779-4:2010

ICS: 11.040.40

Descriptors: implants, surgery, hydroxyapatite, test method, coating adhesion strength

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Committee representation

The Industry Standards Committee on Medical Devices and Facilities for Healthcare (ISC R) under whose authority this Malaysian Standard was adopted, comprises representatives from the following organisations:

Association of Malaysia Medical Industries
Atomic Energy Licensing Board
Biomedical Engineering Association Malaysia
Department of Standards Malaysia
Federation of Malaysian Manufacturers
Institute for Medical Research
Malaysia Medical Device Association
Malaysian Association of Standards Users
Malaysian Medical Association
Malaysian Nuclear Agency
Malaysian Organisation of Pharmaceutical Industry
Malaysian Rubber Board
Malaysian Rubber Export Promotion Council
Ministry of Health Malaysia
Ministry of Health Malaysia (Medical Device Bureau)
Pharmaceutical Association of Malaysia
Radiation Physics, Biophysics and Medical Physics Sub-Group of Institute of Physics Malaysia
SIRIM Berhad (Secretariat)
SIRIM QAS International Sdn Bhd
Universiti Kebangsaan Malaysia
Universiti Teknologi Malaysia

The Technical Committee on Implants for Surgery which supervised the adoption of the ISO Standard consists of representatives from the following organisations:

Academy of Medicine of Malaysia
Association of Malaysia Medical Industries
Association of Private Hospitals of Malaysia
Malaysia Medical Device Association
Malaysian Dental Association
Malaysian Medical Association
Malaysian Orthopaedic Association
Ministry of Health Malaysia
Permuafakatan Pengilang Biomedikal Bumiputra
SIRIM Berhad (Advanced Materials Research Centre)
SIRIM Berhad (Secretariat)
Universiti Islam Antarabangsa Malaysia
Universiti Sains Malaysia

The Working Group on Hydroxyapatite which recommended the adoption of the ISO Standard consists of representatives from the following organisations:

Malaysian Nuclear Agency
SIRIM Berhad (Advanced Materials Research Centre)
SIRIM Berhad (Secretariat)
Universiti Islam Antarabangsa Malaysia
Universiti Sains Malaysia

NATIONAL FOREWORD

The adoption of the ISO Standard as a Malaysian Standard was recommended by the Working Group on Hydroxyapatite under the authority of the Industry Standards Committee on Medical Devices and Facilities for Healthcare.

This Malaysian Standard is identical with ISO 13779-4:2002, *Implants for surgery - Hydroxyapatite - Part 4: Determination of coating adhesion strength*, published by the International Organization for Standardization (ISO). However, for the purposes of this Malaysian Standard, the following apply:

a) in the source text, "this International Standard" should read "this Malaysian Standard";

b) the comma which is used as a decimal sign (if any), to read as a point; and

c) reference to International Standards should be replaced by corresponding Malaysian Standards as follows:

Referenced International Standards	Corresponding Malaysian Standards
ISO 7500-1:1999, *Metallic materials - Verification of static uniaxial testing machines - Part 1: Tension/compression testing machines - Verification and calibration of the force-measuring system*	MS ISO 7500-1:1999, *Metallic materials - Verification of static uniaxial testing machines - Part 1: Tension/compression testing machines - Verification and calibration of the force-measuring system*

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

NOTE. IDT on the front cover indicates an identical standard i.e. a standard where the technical content, structure, and wording (or is an identical translation) of a Malaysian Standard is exactly the same as in an International Standard or is identical in technical content and structure although it may contain the minimal editorial changes specified in clause 4.2 of ISO/IEC Guide 21-1.

INTERNATIONAL STANDARD

ISO 13779-4

First edition
2002-05-01

Implants for surgery — Hydroxyapatite —

Part 4: Determination of coating adhesion strength

Implants chirurgicaux — Hydroxyapatite —

Partie 4: Détermination de la résistance à l'adhésion du revêtement

Reference number
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Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 3.

The main task of technical committees is to prepare International Standards. Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

Attention is drawn to the possibility that some of the elements of this part of ISO 13779 may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights.

International Standard ISO 13779-4 was prepared by Technical Committee ISO/TC 150, *Implants for surgery*, Subcommittee SC 1, *Materials*.

ISO 13779 consists of the following parts, under the general title *Implants for surgery — Hydroxyapatite*:

— *Part 1: Ceramic hydroxyapatite*

— *Part 2: Coatings of hydroxyapatite*

— *Part 3: Chemical analysis and characterization of cristallinity and phase purity*

— *Part 4: Determination of coating adhesion strength*

Future parts will deal with other relevant aspects of implant material based on hydroxyapatite.