



MALAYSIAN STANDARD

**MS ISO 21534:2010
(CONFIRMED:2015)**

Non-active surgical implants - Joint replacement implants - Particular requirements (ISO 21534:2007, IDT)

ISO 21534:2007 is endorsed as Malaysian Standard with the reference number MS ISO 21534:2010.

ICS: 11.040.40

Descriptors: implants, joint replacement implants, surgery, non-active, requirements, design, sterilization, packaging, labelling, marking, use

NOTE. This Malaysian Standard has been reviewed and confirmed as being current.

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

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

Malaysian Orthopaedic Association
Ministry of Health Malaysia
SIRIM Berhad (Secretariat)
Universiti Islam Antarabangsa Malaysia

MS ISO 21534:2010

NATIONAL FOREWORD

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

This Malaysian Standard is identical with ISO 21534:2007, *Non-active surgical implants - Joint replacement implants - Particular requirements*, 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 14155-1, *Clinical investigation of medical devices for human subjects - Part 1: General requirements*

MS ISO 14155-1, *Clinical investigation of medical devices for human subjects - Part 1: General requirements*

ISO 14630, *Non-active surgical implants - General requirements*

MS ISO 14630, *Non-active surgical implants - General requirements*

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.

**Non-active surgical implants — Joint
replacement implants — Particular
requirements**

*Implants chirurgicaux non actifs — Implants de remplacement
d'articulation — Exigences particulières*



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