



# 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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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  
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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.

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

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



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