MALAYSIAN STANDARD

MS 2752:2022

Prosthetic and orthotic devices - Code of practice

ICS: 11.040.01

Descriptors: medical device, medical electrical equipment, code of practice, biomedical engineering, maintenance, services, active medical device, testing, commissioning, acceptance

© Copyright 2022

DEPARTMENT OF STANDARDS MALAYSIA

Preview Only

DEVELOPMENT OF MALAYSIAN STANDARDS

The **Department of Standards Malaysia (Standards Malaysia)** is the national standards and accreditation body of Malaysia.

The main function of Standards Malaysia is to foster and promote standards, standardisation and accreditation as a means of advancing the national economy, promoting industrial efficiency and development, benefiting the health and safety of the public, protecting consumers, facilitating domestic and international trade and furthering international cooperation in relation to standards and standardisation. The use of Malaysian Standards is voluntary except in so far as they are made mandatory by regulatory authorities by means of regulations, local by-laws or any other similar ways.

Malaysian Standards (MS) are developed through consensus by committees which comprise balanced representation of producers, users, consumers and others with relevant interests, as may be appropriate to the subject at hand. The development of a standard as a Malaysian Standard is governed by the Standards of Malaysia Act 1996 [Act 549]. Section 18A of the act stipulated that, all Malaysian Standards are owned by the Government of Malaysia and no part of a Malaysian Standard can be reproduced in any form without the written permission of the Director General.

For further information on Malaysian Standards, please contact:

Department of Standards Malaysia
Level 4 – 7, Tower 2, Menara Cyber Axis
Jalan Impact, Cyber 6
63000 Cyberjaya
Selangor Darul Ehsan
MALAYSIA

Tel: 60 3 8008 2900
Fax: 60 3 8008 2901
http://www.jsm.gov.my
E-mail: central@jsm.gov.my

Preview Only

Contents

Page

Committee representation iii
Foreword iv
1 Scope 1
2 Normative references 1
3 Terms and definitions 3
4 Prosthetic and orthotic devices 5
5 Referral and appointment 6
6 Assessment 7
7 Specification selection 8
8 Funding and ordering 9
9 Device design and preparation 10
10 Fabrication and fitting 12
11 Patient education and training on devices 13
12 Device delivery, outcome evaluation and follow up 13
13 Maintenance and repair 15
Annex A (informative) Prosthetics and orthotics service unit 16
Annex B (informative) Prosthetics and orthotics devices 19
Annex C (informative) Prosthetics and orthotics medical devices design 31
Annex D (informative) Prosthetic limb checkout assessment for fitting and follow-up 43
Annex E.1. Clinical evaluation 46
Annex E.2. Technical evaluation by CPO 47
Annex E.3. Perception & experience evaluation 48
Annex E.4. Socio-Economic evaluation 52

Figure

Figure A.1. Example of P&O Plan Layout 18

Table

Table B.1. Example of nomenclature for lower limb prostheses 22
Table B.2. Example of nomenclature for lower limb orthoses 24

Preview Only

© STANDARDS MALAYSIA 2022 - All rights reserved

Contents *(continued)*

Table B.3. Table 3 Example of nomenclature for upper limb prostheses……26
Table B.4. Example of nomenclature for upper limb orthoses…… . 29

Preview Only

© STANDARDS MALAYSIA 2022 - All rights reserved

Committee representation

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

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

The Technical Committee on Code of Practice for Medical Devices and Healthcare Facilities (TC/R/10) which supervised the development of this Malaysian Standard consists of representatives from the following organisations:

Association of Private Hospitals of Malaysia
Biomedical Engineering Association Malaysia
Department of Standards Malaysia (Secretariat)
Edgenta Mediserve Sdn Bhd
Jabatan Kerja Raya Malaysia (Cawangan Kejuruteraan Elektrik)
KPJ Healthcare Berhad
Malaysia Medical Device Association
Malaysian Medical Association
Medical Device Authority, Ministry of Health Malaysia
Medical Electronic Engineering Association Malaysia
Medivest Sdn Bhd
Ministry of Health Malaysia (Engineering Services Division)
Malaysian Society for Quality in Health
Radicare (M) Sdn Bhd
The Institution of Engineers, Malaysia
Universiti Kebangsaan Malaysia (Faculty of Health Sciences)
Universiti Kebangsaan Malaysia Medical Centre
Universiti Malaya (Department of Biomedical Engineering)
Universiti Malaya Medical Centre
Universiti Sains Malaysia (Department of Development)
Universiti Teknologi Malaysia (Faculty of Biosciences and Medical Engineering)

Preview Only

© STANDARDS MALAYSIA 2022 - All rights reserved

Foreword

This Malaysian Standard was developed by the Technical Committee on Code of Practice for Medical Devices and Healthcare Facilities (TC/R/10) under the authority of the National Standards Committee on Medical Devices and Facilities for Healthcare (NSC R).

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

Preview Only

© STANDARDS MALAYSIA 2022 - All rights reserved