# MALAYSIAN STANDARD

MS 2636:2019

## Halal medical device – General requirements



ICS: 11.040.01

Descriptors: halal, medical device, requirements, compliance, certification



DEPARTMENT OF STANDARDS MALAYSIA

# DEVELOPMENT OF MALAYSIAN STANDARDS

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## Committee representation

The Industry Standards Committee on Halal Standards (ISC I) under whose authority this Malaysian Standard was developed, comprises representatives from the following organisations:

Department of Chemistry Malaysia
Department of Islamic Development Malaysia
Department of Standards Malaysia
Department of Veterinary Services
Federal Agricultural Marketing Authority
Federation of Malaysian Manufacturers
Halal Industry Development Corporation
Institute of Islamic Understanding Malaysia
Institute of Quality Malaysia
International Islamic University Malaysia
Malaysian Agricultural Research and Development Institute
Malaysian Association of Standards Users
Ministry of Domestic Trade and Consumer Affairs
Ministry of Health Malaysia (Food Safety and Quality Division)
Ministry of Health Malaysia (Medical Device Authority)
Ministry of Health Malaysia (National Pharmaceutical Regulatory Agency)
Ministry of International Trade and Industry
Muslim Consumers' Association of Malaysia
National Metrology Institute of Malaysia
Royal Customs Department
Universiti Sains Islam Malaysia

The Working Group on Halal Medical Devices which developed this Malaysian Standard consists of representatives from the following organisations:

Association of Malaysian Medical Industries
Department of Islamic Development Malaysia, Halal Hub Division
Department of Islamic Development Malaysia, Planning and Research Division
Department of Standards Malaysia (Secretariat)
Halal Industry Development Corporation
Malaysia Medical Device Association
Malaysian Pharmaceutical Society
Ministry of Defence Malaysia, Malaysian Armed Forces Headquarters (Health Services Division)
Ministry of Health Malaysia (Medical Device Authority)
Ministry of Health Malaysia (National Pharmaceutical Regulatory Agency)
Muslim Consumers Association of Malaysia
Universiti Sains Malaysia

**Co-opted members:**

Academy of Contemporary Islamic Studies, Universiti Teknologi MARA
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Duopharma Biotech Bhd.
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Ideal Healthcare Sdn Bhd
Industrial Biotechnology Research Centre, SIRIM Berhad
Pharmaniaga Berhad
Renal Laboratories Sdn Bhd
UWC Healthcare MFG (M) Sdn Bhd



 

## Foreword

This Malaysian Standard was developed by the Working Group on Halal Medical Devices under the authority of the Industry Standards Committee on Halal Standards.

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

## Introduction

The Malaysian Standards relating to halal have been developed to meet the challenges of the growing demand for halal products and services, to complement the halal ecosystem within Malaysia. This standard was formulated based on the concept of halal built-in and used by existing competent authorities towards halal certification.

Halal built-in is a systematic approach to halal product development which begins with predefined objectives by the management. It embeds or integrates the requirements of halal as part of the overall management and control systems. It includes all aspect of manufacturing/ production, from strategy/ planning to research and development to raw material sourcing until delivery of finished product to its point of purchase. This ensures continuous compliance to the specific halal requirements and the aspects of product safety, performance, efficacy/effectiveness and quality, along with the hygienic aspects in manufacturing and handling of the halal product.

Halal requirements are as stated by *Shariah* and *fatwa* that are incorporated into halal standards which is in the form of the standards developed by the Department of Standards Malaysia. Halal should be built-in into the entire system.

Obtaining halal certification is a business strategy and is seen as a value added element. Since, the main requirements of all medical devices are there its safety and performance as such, all medical devices have to comply with the Medical Device Act 2012 (Act 737) before they can be certified halal.