

MALAYSIAN STANDARD

MS 2636:2019

Halal medical device – General requirements

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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

Co-opted members:

Academy of Contemporary Islamic Studies, Universiti Teknologi MARA Ain Medicare Sdn Bhd Allen Healthcare Products (M) Sdn Bhd APS Medical Sdn Bhd B. Braun Medical Industries Sdn Bhd Duopharma Biotech Bhd. Fresenius Medical Care Malaysia Sdn Bhd GranuLab (M) Sdn Bhd 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.