HALALSPHERE

International Islamic University Malaysia - INHART

Understanding the Malaysian halal certification framework for medical devices

Nur Azira Tukiran*, Katrul Nadia Basri and Anis Najiha Ahmad

International Institute for Halal Research and Training (INHART), Level 3, Block A, KICT Building, International Islamic University Malaysia (IIUM), Jalan Gombak, 53100, Gombak, Selangor, Malaysia.
*Corresponding author: E-mail address: aziratukiran@iium.edu.my

Received: 27/7/2026
Accepted: 30/7/2026
Published: 31/7/2026

Keywords:
Halal medical devices; Halal certification; MPPHM 2020; MHMS 2020; MS 2636:2019; Medical device authority

Abstract

This short communication analyses Malaysia's halal certification framework for medical devices using document analysis of the *Manual Prosedur Pensijilan Halal Malaysia (Domestik) 2020* (MPPHM), as amended in 2026, the Malaysian Halal Management System 2020 (MHMS), MS 2636:2019, and relevant medical-device legislation. The analysis shows that halal certification functions as an additional assurance layer built upon regulatory compliance. Within this framework, MPPHM establishes regulatory eligibility through registration with the Medical Device Authority (MDA) or an exemption, and through establishment licensing. MHMS provides halal management through the Halal Assurance System (HAS) or Internal Halal Control System (IHCS). At the same time, MS 2636:2019 defines technical requirements for materials, manufacturing, premises, contamination control, packaging, traceability, and internal audit. Collectively, these documents integrate regulatory, certification, management, and technical controls to safeguard the halal integrity, safety, and quality of medical devices.

1. Introduction

Medical devices comprise a broad range of instruments, implants, reagents, materials, software, and related articles intended for purposes such as diagnosis, prevention, monitoring, or treatment (Medical Device Act 2012, 2012). A specialised regulatory system governs their safety, quality, and performance. In Malaysia, this system is established principally through the Medical Device Act 2012 (Act 737), the Medical Device Regulations 2012, and subsequent subsidiary legislation issued under the Act. The Medical Device Authority (MDA), established under the Medical Device Authority Act 2012 (Act 738), administers and enforces the medical-device regulatory framework (Medical Device Authority Act 2012, 2012).

Halal considerations arise when a device contains, incorporates, or is manufactured using materials whose origin or processing may be uncertain from a Shariah perspective. Examples identified under the Malaysian halal certification procedure include sutures, humidifiers, dental floss, selected solutions, grafts, implants, and prosthetic products. The concern is not limited to the visible finished device. Raw materials, components, processing aids, manufacturing equipment, packaging materials, storage, and distribution may also affect halal integrity (Department of Islamic Development Malaysia [JAKIM], 2026).

Malaysia addresses these concerns through a framework that combines medical device regulation, halal certification procedures, internal halal management, and product-specific technical requirements. However, the functions of the relevant documents are sometimes discussed separately, which may create uncertainty among manufacturers and halal practitioners. The legal basis for the certification and marking of products as halal is provided by the Trade Descriptions (Certification and Marking of Halal) Order 2011, which recognises JAKIM and the respective State Islamic Religious Councils or Departments as competent authorities for halal certification (Trade Descriptions (Certification and Marking of Halal) Order 2011).

This short communication therefore explains the complementary roles of the *Manual Prosedur Pensijilan Halal Malaysia (Domestik) 2020* (MPPHM 2020), as amended by *Pekeliling Pensijilan Halal Malaysia Bilangan 1 Tahun 2026*, the Malaysian Halal Management System 2020 (MHMS 2020), and MS 2636:2019 Halal Medical Device - General Requirements. It also positions these halal requirements within the regulatory foundation provided by Act 737, the Medical Device Regulations 2012, and ISO 13485:2016.

2. Methodology

A descriptive document analysis was conducted using the primary documents governing the halal certification and regulatory control of medical devices in Malaysia. The analysis included the Medical Device Act 2012 (Act 737), the Medical Device Regulations 2012, the Medical Device (Duties and Obligations of Establishments) Regulations 2019, the Medical

Device (Exemption) Order 2024, the Medical Device (Compounding of Offences) Regulations 2024, the Medical Device (Amendment) Regulations 2025, the Medical Device (Designated Medical Device) Order 2026, the Trade Descriptions (Certification and Marking of Halal) Order 2011, the second edition of MDA Guidance Document MDA/GD/0027 on establishment licensing, MPPHM 2020 as amended in 2026, MHMS 2020, MS 2636:2019 and ISO 13485:2016. The documents were examined according to four functional dimensions reflected in the structure of the following discussion: (i) medical-device regulatory eligibility, (ii) halal certification procedures under MPPHM 2020 as amended in 2026, (iii) internal halal governance under MHMS 2020, and (iv) technical and operational controls under MS 2636:2019. The objective was not to compare the documents clause by clause, but to show how their different functions combine into a coherent certification framework.

3. The regulatory foundation for medical devices

The Medical Device Authority (MDA), established under the Medical Device Authority Act 2012 (Act 738), is responsible for regulating medical devices, the medical device industry, and related activities in Malaysia (Medical Device Authority Act 2012, 2012). Halal certification does not replace compliance with medical device regulations. Section 5 of the Medical Device Act 2012 (Act 737) establishes the requirement for medical-device registration, while Section 15 addresses establishment licensing (Medical Device Act 2012, 2012).

The Medical Device Regulations 2012 provide further requirements for conformity assessment, device registration, establishment licensing, and labelling. Conformity assessment covers the quality management system, post-market surveillance system, technical documentation, and declaration of conformity. These regulatory controls are principally directed at the safety, quality, and performance of medical devices (Medical Device Regulations 2012).

Post-market responsibilities are further governed by the Medical Device (Duties and Obligations of Establishments) Regulations 2019, which prescribe requirements for complaint handling, distribution records, mandatory problem reporting, field corrective action, and medical-device recall (Medical Device (Duties and Obligations of Establishments) Regulations 2019, 2019).

More recent subsidiary legislation has refined specific aspects of the medical-device regulatory framework. The Medical Device (Exemption) Order 2024 specifies exemptions from selected regulatory requirements and revokes the previous 2016 order. This instrument is relevant to halal certification because MPPHM 2020, as amended in 2026, permits an exemption letter from the MDA for devices that do not require device registration. The Medical Device (Compounding of Offences) Regulations 2024 identify offences that may be compounded. The Medical Device (Amendment) Regulations 2025 revise the application and registration fees for Class A medical devices with effect from 1 January 2026. The Medical Device (Designated Medical Device) Order 2026 specifies designated medical devices and their permitted uses. These instruments refine particular aspects of medical-device regulation but do not alter the principal halal certification requirements (Medical Device (Exemption) Order 2024, 2024; Medical Device (Compounding of Offences) Regulations 2024, 2024; Medical Device (Amendment) Regulations 2025, 2025; Medical Device (Designated Medical Device) Order 2026, 2026).

The second edition of the establishment licensing guidance further distinguishes the regulatory roles of manufacturers, authorised representatives, importers, and distributors (MDA, 2022). It specifies that a manufacturer must obtain quality management system certification to MS ISO 13485:2017 or ISO 13485:2016. In contrast, an authorised representative, importer, or distributor must obtain a certificate of conformity to Good Distribution Practice for Medical Devices (GDPMD) (MDA, 2022). For a local manufacturing premise seeking halal certification, the validity and appropriate scope of the MDA establishment licence are therefore important.

Taken together, these requirements establish the regulatory foundation for medical devices before halal certification is considered. Device registration, establishment licensing, conformity assessment, quality management, and post-market controls primarily address the safety, quality, and performance of medical devices. However, regulatory compliance alone does not confirm halal status. Halal certification, therefore, introduces an additional assurance layer that addresses material sources, manufacturing practices, contamination control, and ongoing halal integrity, as discussed in the following section.

4. Components of the halal certification framework

4.1 MPPHM 2020 as amended in 2026: Certification eligibility and procedure

MPPHM governs the application and administration of Malaysian halal certification. For the medical-device scheme, it links halal certification directly to regulatory status. Each device must possess a valid Medical Device Registration Certificate issued by the MDA or a letter confirming exemption from registration. In addition, the premises that process and manufacture the device must possess a valid MDA establishment licence (JAKIM, 2026).

The procedure also identifies the types of devices that may be considered under the scheme. These include devices for which the source of manufacturing materials or ingredients creates halal uncertainty, particularly materials associated with animals or alcohol. The listed examples include sutures, humidifiers, and dental floss, as well as liquid products such as dialysis or haemodialysis solutions, saline solutions, lubricants, wound-irrigation solutions, contact-lens solutions, and eye lubricants. Other examples include skin or surgical mesh, bone and vascular grafts, heart valves, stents, cochlear implants, intraocular lenses, and prosthetic devices. Eligibility remains subject to approval by the halal competent authority (JAKIM, 2026).

MPPHM requires compliance with MS 2636:2019, Act 737, the Medical Device Regulations 2012, and other current legislation enforced by the relevant authorities. It also specifies Muslim personnel and halal management requirements according to industry size. Large and medium industries must permanently appoint at least two Malaysian Muslim employees to the processing area during operations or shifts, appoint a Halal Executive at each branch, establish an Internal Halal Committee where required, and implement a Halal Assurance System (HAS). A small industry must appoint at least one such Muslim employee, appoint a Halal Supervisor, and implement an Internal Halal Control System (IHCS). A micro industry must appoint at least one such Muslim employee and

implement an IHCS (JAKIM, 2026).

4.2 MHMS 2020: Maintaining internal halal assurance

MHMS explains how a certified company develops, implements, and maintains internal halal control. It provides two levels of management system: IHCS for small and micro industries and HAS for large and medium industries. The distinction allows the depth of documentation and organisational control to be proportionate to the scale of the operation while maintaining essential halal safeguards.

IHCS represents the minimum internal control arrangement and includes a halal policy, a raw-material control or halal-risk control procedure, and a traceability procedure. HAS is more comprehensive. It includes a documented HAS manual, halal policy, Internal Halal Committee, halal internal audit, halal risk control, raw-material control, halal training, traceability, and management review. The company is responsible for ensuring that these controls remain effective throughout the validity of the Malaysian Halal Certification Certificate (JAKIM, 2020).

For medical-device manufacturing, the MHMS approach is especially relevant because material and component supply chains can be complex. Traceability should allow the company to identify materials and products through receiving, processing, storage, and distribution. Halal risk control requires identifying Halal Control Points, control mechanisms, responsible personnel, monitoring frequency, corrective actions, and records. Thus, MHMS converts the certification requirements into continuing organisational responsibilities.

4.3 MS 2636:2019: Technical and operational requirements

MS 2636:2019 specifies requirements for the manufacturing and handling of medical devices eligible for halal certification. The standard adopts a halal-built-in approach, whereby halal requirements are incorporated into product development and the overall management and control system, rather than assessed only at the end of production. The standard states that its requirements are to be incorporated with Act 737 and MS ISO 13485 as enforced by the relevant authority (Department of Standards Malaysia, 2019).

The standard requires that the medical device submitted for halal certification be registered with the competent medical device authority. It also requires a documented halal management system, appropriate Muslim personnel or an Internal Halal Committee, continuing halal training, adequate resources, and maintained records. The main Halal Control Points include sources of materials, equipment, and utilities used during manufacturing. Evidence of material origin may include recognised halal certificates, specifications describing the materials and processing methods, and manufacturing formulae or processing instructions (Department of Standards Malaysia, 2019).

All materials used in manufacturing must comply with halal requirements and be free from *najis*. The standard addresses synthetic materials, natural materials, and genetically modified sources, as well as manufacturing premises, equipment, manufacturing and storage areas, transportation, quality-control activities, packaging, and labelling. Controls are intended to prevent contact or cross-contamination with non-halal materials. Where a facility or equipment has previously been used for *najis mughallazah*, cleansing by *sertu* is required under the stated conditions before conversion to a dedicated halal line (Department of Standards Malaysia, 2019).

MS 2636:2019 also extends halal assurance beyond production. Distribution must minimise risks to halal integrity; outsourced activities must be defined, agreed and controlled through written arrangements; and a post-market halal surveillance mechanism should be established. Complaints involving halal non-conformity must be investigated and corrective action taken. An internal audit is required annually to monitor compliance with halal requirements and MS ISO 13485 (Department of Standards Malaysia, 2019). These requirements connect halal integrity with the established quality management practices in the medical device sector.

5. An integrated framework

The three halal documents perform different but complementary functions. MPPHM determines whether the product and applicant meet the certification conditions and prescribes the administrative and scheme-specific requirements. MHMS establishes the internal governance needed to maintain halal assurance. MS 2636:2019 provides the technical requirements for materials, facilities, and operations. Their complementary functions are summarised in Table 1.

Collectively, these documents form a complementary and layered framework. The applicable MDA requirements provide the regulatory foundation for device registration, establishment licensing, safety, quality, and performance. MPPHM 2020, as amended in 2026, establishes the eligibility and procedural requirements for halal certification, while MHMS 2020 and MS 2636:2019 provide the internal governance and technical controls required to demonstrate and maintain halal compliance. Following certification, traceability, internal audit, complaint handling, and post-market controls support continuing halal assurance.

6. Practical implications, challenges, and future directions

MDA registration confirms regulatory compliance relating to the medical-device registration framework, but it does not confirm that the device is halal. Conversely, halal certification should not be interpreted as a substitute for regulatory assessment of safety and performance. The two systems address distinct but related expectations. This distinction is important in product communication so that a halal mark is not presented as a general regulatory endorsement.

Within this complementary framework, material documentation becomes a central halal control point. Medical devices may contain several layers of materials, including primary components, coatings, adhesives, lubricants, solvents, processing aids, and packaging materials. The halal status of a finished product, therefore, depends on sufficient information from the supply chain. The manufacturer should be able to identify the original material producer, the material composition, the processing method, and relevant supporting evidence. Changes in suppliers, formulations, or manufacturing processes should trigger an assessment of their potential effects on both product quality and halal integrity.

Halal controls may be integrated with the existing medical device quality management system. ISO 13485 requires documented quality processes, purchasing controls, traceability where applicable, internal audits, corrective actions, and record retention (International Organization for Standardization, 2016). These structures can support halal assurance when halal-specific criteria are incorporated. For example, supplier approval may include verification of halal-critical materials, while change control may include an assessment of halal impact. Quality and halal audits may also be coordinated when examining related evidence, while preserving their distinct objectives, criteria, and required records.

Table 1: Complementary functions of the principal documents in the Malaysian halal medical-device framework

Document	Primary function	Key contribution
MPPHM 2020, as amended in 2026	Certification procedure and scheme eligibility	Requires valid MDA device registration or exemption, a valid establishment licence, an eligible product scope, Muslim personnel, and implementation of MHMS.
MHMS 2020	Internal halal management and control	Provides HAS for large and medium industries and IHCS for small and micro industries, including risk control, traceability, training, audit, and records.
MS 2636:2019	Technical manufacturing and handling requirements	Controls materials, components, premises, equipment, manufacturing, contamination, packaging, storage, distribution, outsourcing, and post-market halal issues.
Act 737, Medical Device Regulations 2012, post-market regulations, MDA/GD/0027, and ISO 13485:2016	Regulatory and quality foundation	Addresses device registration, conformity assessment, establishment roles and licensing, post-market obligations, and quality management for safety and performance.

However, a uniform assessment may not be appropriate for all medical devices. A dialysis solution, an animal-derived bone graft, and a synthetic prosthetic component may involve different materials, processes, and halal risks. Product assessment should therefore consider the intended purpose, material and component origins, processing aids, manufacturing processes, outsourced operations, and potential contamination pathways. Potential implementation challenges include obtaining sufficient evidence from international suppliers, addressing differences in certification requirements across jurisdictions, and developing personnel with combined expertise in halal requirements and medical device regulations (Astiwara, 2023; Jailani & Jezani, 2024).

Recent studies indicate growing interest in halal medical devices for religious assurance, medical tourism, and international market opportunities (Jamal & Jamaludin, 2024; Sarisae *et al.*, 2023). Nevertheless, empirical research involving medical-device manufacturers remains limited. Future research should examine supplier documentation practices, product-specific Halal Control Points, coordination with ISO 13485, and multidisciplinary human talent development. Comparative studies across jurisdictions may also support clearer guidance and greater international harmonisation of halal medical-device certification.

7. Conclusion

Malaysia's halal certification framework for medical devices is not based on a single document. It is formed through the interaction of medical-device legislation and four complementary functions: regulatory eligibility, halal certification procedure, internal halal governance, and technical control. MPPHM 2020, as amended in 2026, links certification to valid MDA device registration or exemption and to establishment licensing, defines eligible products, and specifies scheme requirements. MHMS 2020 provides the HAS or IHCS needed to maintain internal control, while MS 2636:2019 translates Shariah requirements into controls for materials, facilities, manufacturing, packaging, distribution, and post-market activities. Reading these documents together clarifies that halal assurance complements rather than replaces safety, quality, and performance requirements. Effective implementation, therefore, depends on coordinated regulatory compliance, traceable material evidence, competent halal personnel, and integration of halal controls into the existing medical-device quality management system.

Conflict of interest

The authors declare no competing interests.

AI declaration

Artificial Intelligence (AI) tools, including ChatGPT (OpenAI, San Francisco, CA), were used to assist with language editing, improve sentence structure, and clarify grammar during manuscript preparation. The authors reviewed, verified, and take full responsibility for the accuracy and integrity of the content. No AI tools were used for data analysis, result interpretation, or scientific conclusions.

Author contribution

Author 1: project administration, conceptualization, methodology, formal analysis, investigation, data curation, writing original draft preparation, writing, reviewing, and editing. Author 2: writing, reviewing, and editing. Author 3: writing, reviewing, and editing.

References

Astiwara, E. M. (2023). Halal certification regulation on health products: A global comparative study. International Journal of Science and Society, 5(3), 470–483. https://doi.org/10.54783/ijsoc.v5i3.1422

Department of Islamic Development Malaysia. (2020). Malaysian Halal Management System 2020 (MHMS 2020).

Department of Islamic Development Malaysia. (2026). *Pekeliling Pensijilan Halal Malaysia Bilangan 1 Tahun 2026: Pindaan Manual Prosedur Pensijilan Halal Malaysia (Domestik) 2020*.

Department of Standards Malaysia. (2019). Halal medical device - General requirements (MS 2636:2019).

International Organisation for Standardisation. (2016). Medical devices - Quality management systems -Requirements for regulatory purposes (ISO 13485:2016).

Jailani, M. D. A., & Jezani, S. N. (2024). Halal in the medical and pharmaceutical sector: Recent issues, standard guidelines, and state-of-the-art. In: Rahman, N.A.A., Ali, M.H. (eds) Emerging Technology and Crisis Management in the Halal Industry. Springer, Singapore. https://doi.org/10.1007/978-981-97-1375-2_14

Jamal, A. Z. A., & Jamaludin, M. A. (2024). Halal medical tourism and reproductive care and services: An overview of the Malaysian marketplace. Journal of Halal Industry & Services, 7(1). https://doi.org/10.36877/jhis.a0000528

Medical Device (Amendment) Regulations 2025 (Malaysia).

Medical Device (Compounding of Offences) Regulations 2024 (Malaysia).

Medical Device (Designated Medical Device) Order 2026 (Malaysia).

Medical Device (Duties and Obligations of Establishments) Regulations 2019 (Malaysia).

Medical Device (Exemption) Order 2024 (Malaysia).

Medical Device Act 2012 (Act 737) (Malaysia).

Medical Device Authority Act 2012 (Act 738) (Malaysia).

Medical Device Authority. (2022). Licensing for establishment (MDA/GD/0027, 2nd ed.).

Medical Device Regulations (2012). (Malaysia).

Sarisae, S., Benrit, P., & Salaeh, N. (2023). The need for halal certification of medical devices: A case study of Thailand. Journal of Halal Science and Technology, 2(1), 32–39. https://doi.org/10.59202/jhst.v2i1.664

Trade Descriptions (Certification and Marking of Halal) Order 2011 (Malaysia).