

The **HEALTH**

Taxed and Tariffed

With new service taxes on non-citizens and rising US tariffs on medical exports, Malaysia's healthcare sector faces cost pressures, compliance hurdles, and critical decisions on sustainability.

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Nursing on the brink

- Malaysia faces a potential nursing shortfall of nearly 60 per cent by 2030, with a need for 270,223 nurses compared to the current 120,667. - **P12-13**

Beyond the eye chart

- JNJVISONPRO stands out as a beneficial tool for ECPs, encouraging continuous professional development. - **P16-18**

Behind the scalpel

- Surgeons face chronic stress, emotional fatigue, and isolation - leading to high rates of burnout, depression and anxiety. - **P24**

Decoding halal medical devices

- The global medical devices industry is expanding rapidly, ensuring halal compliance in these devices is crucial.
- Malaysia has pioneered the development of the Malaysian Standard MS 2636:2019, which provides comprehensive guidelines for halal medical devices.
- Innovations like plant-based biomaterials and blockchain for supply chain transparency present significant opportunities.



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THE global medical devices market is experiencing significant growth, with its value projected to rise from approximately US\$542 billion in 2024 to nearly US\$887 billion by 2032 (Business Today Editorial, 2024).

Medical devices are used in the diagnosis, prevention, monitoring, treatment, or alleviation of disease or injury. The increasing prevalence of chronic illnesses and the global shift toward early detection have driven the rising adoption of advanced medical technologies.

But within this growth lies a quieter question: How do these innovations align with Islamic principles? For Muslims, medical care is not just about function—it is about faith. As the field advances, halal compliance in medical devices is no longer a secondary concern; it has become a primary consideration. It is an emerging standard.

HALAL DEVICES

As demand for medical devices continues to rise, ensuring their halal compliance becomes essential—especially for Muslim users. In Islam, a product is considered halal (permissible) when it is lawful and toyyib (good), as stated in Qur'an 2:168, and complies with Islamic legal and ethical principles.

"O mankind, eat from whatever is on earth [that is] lawful (halal) and good (toyyib) and do not follow the footsteps of satan. Indeed, he is to you a clear enemy" (Quran, Al-Baqarah, 2:168)

Beyond ingredients, halal compliance also encompasses the processing, manufacturing, handling, and storage of a product. The entire supply chain must be free from impure or haram materials, directly or indirectly. Equipment used must not have been exposed to non-halal substances unless it has undergone proper Islamic cleansing (sertu) procedures.

The application of halal principles in medical devices includes evaluating raw materials, manufacturing environments, and ethical integrity. For example, the use of human body parts without medical necessity or ethical justification is prohibited under Islamic law. In this context, halal is not limited to ingredients—it encompasses the purpose, integrity, and moral framework of the entire product.

Decoding Halal Medical Devices

Growth • Hurdles • Horizon



GLOBAL MARKET OUTLOOK
2024: USD 542B
2032 (Projected): USD 887B

WHAT MAKES A MEDICAL DEVICE HALAL?

- Free from haram & najis
- Processed, handled & stored according to Islamic principles
- Traceable
- Sertu (cleansing) if cross-contaminated
- Purpose & ethics considered (e.g. no unnecessary use of human parts)



KEY INDUSTRY CHALLENGES

- Global supply chain complexity
- Low consumer awareness
- Limited halal-certified materials
- Inconsistent global regulations
- Low awareness among manufacturers

HORIZON & OPPORTUNITIES

- Halal-compliant biomaterials: Plant-based or synthetic
- Zabihah-sourced gelatin/collagen
- Halal R&D hubs in OIC countries
- Cross-sector collaboration for innovation & export
- Integrating blockchain technology

CONVENTIONAL DEVICES

Many conventional medical devices, especially those used in implants or with coatings, may contain animal-derived substances that raise halal concerns. For example, gelatin, commonly used in capsule coatings or wound dressings, is often sourced from pigs unless otherwise specified.

Similarly, collagen, sutures, or biological implants, such as heart valves, may originate from non-halal animals. To be halal, animal-derived materials must come from animals slaughtered in accordance with Islamic procedures (zabiha). This ensures that the material is both physically safe and halal (permissible).

Alcohol-based substances also pose questions. While alcohol is prohibited for consumption, external medical uses are permissible under specific conditions. Devices involving human-derived tis-

sues, such as bone grafts or skin patches, also present complex halal authentication challenges.

Halal compliance goes beyond materials. The entire production environment, including packaging and logistics, must be free from contamination by non-halal substances. Shared manufacturing lines must be thoroughly cleansed to maintain integrity.

Given the complexities, verifying the halal status of medical devices is crucial—not only to fulfil religious obligations but also to foster consumer trust, expand new markets, and meet rising ethical expectations in global healthcare.

PRINCIPLE TO PRACTICE

Malaysia has taken a pioneering role in formalising the certification of halal medical devices through the introduction of MS 2636:2019, "Halal Medical Devices: General Requirements."

MS 2636:2019 defines a halal medical device as one that is free from haram (forbidden) or najis (impure) substances, is safe for use, and is produced, handled, and stored in accordance with Islamic principles (Department of Standards Malaysia, 2019).

The standard sets precise requirements for sourcing and production, with particular attention given to animal-derived materials, such as gelatin, collagen, or tissue grafts, which must originate from animals slaughtered in accordance with Islamic law. Human-derived materials are only permissible under strict ethical and religious conditions, usually in cases of medical necessity.

A key strength of MS 2636:2019 is its alignment with internationally recognised standards, particularly ISO 13485, which governs quality management systems for medical devices. This integration ensures that halal-certified products do not compromise on safety or performance and meet global regulatory expectations.

Traceability is a critical component of MS 2636:2019, which mandates that every stage of the product's lifecycle, from sourcing to end-user delivery, must be documented and auditable to maintain halal integrity.

Hygiene protocols must align with both Islamic requirements and industrial standards such as Good Manufacturing Practices (GMP). A risk

management framework must also be in place to identify, control, and respond to any threats to the halal status of the product.

In Malaysia, any medical device must be approved by the Medical Device Authority (MDA), as stipulated under the Medical Device Act 2012 (Act 737) and the Medical Device Regulations 2012. These regulations are in place to ensure that all medical devices used within the country meet strict standards of safety, quality, and performance.

HURDLES

Despite having standards in place, implementing halal standards in medical devices faces several notable challenges:

- Global supply chain complexity: Modern medical devices often comprise components sourced from multiple countries, making it difficult to verify the halal status of every material and process involved. This global interconnectivity can obscure the origins of raw materials, mainly when animal-derived ingredients or additives are used.
- Limited technical awareness: Many manufacturers, particularly those outside the Muslim world, may be unfamiliar with Islamic requirements and may not prioritise halal compliance.
- Lack of consumer demand: The lack of consumer awareness regarding the use of halal medical devices presents a significant challenge, as many consumers continue to opt for conventional alternatives. As noted by Noorul Huda Sahari et al. (2021), awareness had the weakest positive correlation with the use of halal medical devices, suggesting that current awareness efforts are insufficient to drive meaningful behavioural change.
- Limited availability of halal alternatives: Developing or sourcing halal-certified options (such as gelatin or collagen derived from permissible sources) can be complex, expensive, or technologically demanding. This discourages many manufacturers from pursuing halal certification.
- Regulatory inconsistency across countries: Although countries like Malaysia have established comprehensive halal medical device standards, other countries, particularly those not adhering to Islamic principles, lack specific guidelines for halal medical devices. This inconsistency creates confusion for international manufacturers and hinders global trade in halal-certified medical devices.

These challenges necessitate greater coordination and the involvement of international regulatory bodies to advance the halal medical device industry sustainably.

OPPORTUNITIES

Despite the challenges facing the halal medical device sector, there are significant opportunities for growth and innovation that can shape its future trajectory. One of the most promising areas lies in the development of Halal-compliant biomaterials.

Biomedical research can be directed toward creating materials derived from plant-based sources or synthetic polymers, which eliminate the ambiguity associated with animal-derived substances. In cases where animal-based components are necessary, switching to halal-slaughtered bovine tissues offers a viable alternative.

Furthermore, countries with strong Islamic economies, such as Malaysia, the United Arab Emirates, and Indonesia,

ers, halal certification bodies, regulators, and end-users, to access real-time, immutable records of origin for each ingredient, as well as processing and certification history.

For example, when a medical device component is sourced, blockchain can log whether it came from a halal-certified supplier, whether it was handled according to Shariah-compliant procedures, and when it received official certification.

This level of visibility enhances trust in halal certification and significantly reduces the risk of fraud, contamination, or non-compliance. Furthermore, blockchain can automate verification through smart contracts, ensuring that only components meeting halal standards proceed to the next stage of production.



have the potential to become global hubs for halal medical devices. These nations can invest in establishing halal-focused research and development ecosystems that encourage innovation while maintaining religious compliance.

Strategic cross-sector collaboration between academia, industry, regulatory bodies, and halal certification agencies can drive the commercialisation of compliant technologies. This can also support the creation of export-oriented solutions that meet international halal standards, positioning these countries as leaders in the global halal medical device market.

BLOCKCHAIN

The application of blockchain technology in halal medical devices represents a transformative advancement in ensuring transparency, traceability, and integrity within the halal supply chain. In the context of halal compliance, especially for medical devices that may contain animal-derived materials or undergo complex global manufacturing processes, verifying Halal status at every stage is crucial.

Blockchain offers a decentralised and tamper-proof ledger system that allows all stakeholders, including manufac-

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GLOBAL STANDARD

The incorporation of halal principles into the medical device industry represents a crucial convergence of faith, ethics, and science. By harmonising Islamic values with ISO-based best practices, the standard offers a dual benefit: it assures Muslim consumers of religious compliance while maintaining high-quality production standards acceptable worldwide.

While still in its infancy, the movement toward halal-certified medical devices responds to a real need in Muslim communities for products that align with their religious beliefs and health values.

It provides manufacturers with a strategic advantage in accessing the global halal market, strengthening consumer confidence, and promoting ethical and transparent supply chains. Success in this domain requires collaboration among stakeholders, including engineers, manufacturers, Shariah experts, regulatory bodies, and policymakers.

With structured guidelines, rigorous certification, and proactive innovation, the future of halal medical devices holds promise not just for Muslims, but for global markets seeking ethical and high-quality healthcare solutions.

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