NIOSHCert | NIOSH CERTIFICATION

MEDICAL DEVICE FULL CONFORMITY ASSESSMENT

ABOUT CONFORMITY ASSESSMENT

Under Section 10 of the Medical Device Act 2012 (Act 737), all medical devices intended for manufacture, import, or distribution in Malaysia must undergo conformity assessment by a registered Conformity Assessment Body (CAB) before registration. This ensures compliance with safety and performance standards to protect public health

- **Full Conformity Assessment**

  Medical devices without prior approval from recognized regulatory authorities or notified bodies must undergo full conformity assessment. This involves a comprehensive evaluation by a registered CAB, as required under Section 7(1)(a) of Act 737.

LATEST UPDATES IN 2025

As of January 15, 2025, the Medical Device (Compounding of Offenses) Regulations 2024 have been enforced. This regulation allows the Medical Device Authority (MDA) to compound specific regulatory offenses, ensuring stricter compliance with Act 737.

Additionally, the second edition of the Guidance Document: Importation of Medical Devices for Personal Use was released in January 2025. This update provides clearer guidelines for individuals importing medical devices for personal use, helping them navigate regulatory requirements effectively.

By adhering to the conformity assessment process, Malaysia continues to uphold high standards for medical devices, reinforcing patient safety and regulatory integrity.

SUSTAINABLE DEVELOPMENT GOALS

3 GOOD HEALTH AND WELL-BEING | 9 INDUSTRY, INNOVATION AND INFRASTRUCTURE | 12 RESPONSIBLE CONSUMPTION AND PRODUCTION | 16 PEACE, JUSTICE AND STRONG INSTITUTIONS

MAIN COMPONENTS

The MDA's Medical Device Conformity Assessment process involves several key components designed to assess the compliance of medical devices with regulatory requirements:

- Documentation Review:
  - The verification process begins with a thorough review of the technical documentation provided by the manufacturer or importer. This includes the device's design, intended use, risk assessment, and compliance with relevant standards.
- Conformity Assessment:
  - Depending on the class of the medical device, the MDA may require a conformity assessment, which could include an audit of the manufacturer's quality management system or an evaluation of the device's clinical data.
- Labelling and Instructions for Use:
  - The MDA verifies that the labeling and instructions for use are clear, accurate, and compliant with regulatory requirements. This is crucial for ensuring that healthcare professionals and patients can use the device safely and effectively.
- Post-Market Surveillance:
  - After a device is verified and allowed on the market, the MDA monitors its performance through post-market surveillance activities. This includes reporting and analyzing adverse events and conducting follow-up inspections.

BEGIN YOUR JOURNEY

1

DETERMINE DEVICE CLASSIFICATION

Classify the medical device according to the rules specified in the First Schedule of the Medical Device Regulation 2012 and the Guidance Document on Classification (MDA/GD-04).

2

SELECT APPROPRIATE CONFORMITY ASSESSMENT ROUTE

- **Full Conformity Assessment:** For devices without prior approval from recognized regulatory authorities.
- **Verification of Conformity Assessment:** For devices already approved by recognized regulatory authorities (e.g., US FDA, EU CE Mark).

3

PREPARE TECHNICAL DOCUMENTATION

Compile evidence of conformity, including:

- ISO 13485 certification
- Post-Market Surveillance (PMS) system
- Essential Principles of Safety and Performance
- Common Submission Dossier Template (CSDT)
- Declaration of Conformity

4

ENGAGE A REGISTERED CAB

- Choose a CAB registered with the MDA to conduct the conformity assessment.
- Apply for the assessment .

5

CAB ASSESSMENT

- Submit the technical documents as per checklist
- The CAB reviews and validates the submitted documentation.
- If requirements are met, the CAB issues a Medical Device Conformity Assessment Report and Certificate of Conformity

6

REGISTER WITH MDA

Submit the conformity assessment report and certificate via the MDA's online system, MeDC@St, to register the medical device.

NIOSHCert aims to create impact

collaboratively

SCAN ME

NIOSH CERTIFICATION SDN. BHD. (NIOSHCert) is a leading national certification body and a wholly owned subsidiary of the National Institute of Occupational Safety and Health (NIOSH), and the Ministry of Human Resources, Malaysia. We have a proven track record of delivering reliable and comprehensive assessments, in conformance with the relevant international standards, codes of practices, guidelines and rules and regulations. Since 2004, NIOSHCert has been a collaboratively partner in the ISO Certification journeys of Malaysia's most successful companies, government bodies, higher learning institutions and SMEs. We have helped clients create impact and give value to the world's communities through providing internationally-recognised certification services. It is our passion and privilege to be the trusted, reliable and transparent partner in helping our clients increase the efficiency and effectiveness of their businesses operations. Testimony to NIOSHCert's emphasis on customer satisfaction, our top 10 clients have been with us for an average of 10 years. OUR COMMITMENT NIOSHCert's business practices are safe, responsible, impartial, and transparent in accordance with our Core Values and ISO 17021 Principles.

SUSTAINABLE DEVELOPMENT GOALS

Realisation of the SDGs require the joint efforts from many parties. The work of NIOSH Certification, and implementation of the management systems certifications offered by NIOSH Certification are aligned with, and contribute to the achievement of the SDGs.

CONTACT US

NIOSH Certification Sdn. Bhd.
7th Floor, NIOSH Tower,
Lot 1, Jalan 15/1, Section 15,
43650 Bandar Baru Bangi,
Selangor Darul Ehsan.

+603.8922.1925 / +6019.210.7656

connect@nioshcert.com.my

www.nioshcert.com.my

Follow NIOSHCERTIFICATION