NIOSHCert | NIOSH CERTIFICATION

MEDICAL DEVICE CONFORMITY ASSESSMENT

(BY WAY OF VERIFICATION)

ABOUT CONFORMITY ASSESSMENT

Medical Device Conformity Assessment is a mandatory process established by the Medical Device Authority (MDA) in Malaysia to ensure that all medical devices distributed and used within the country meet stringent safety, quality, and performance standards. This verification process is part of the broader regulatory framework outlined in the Medical Device Act 2012 (Act 737), which aims to protect public health by ensuring that medical devices are safe and effective for their intended use. The verification process is a critical step in ensuring that only compliant and reliable medical devices are available in the Malaysian market.

BENEFITS

- **Enhanced Patient Safety:** Mandatory product verification ensures that only safe and effective medical devices reach the market, reducing the risk of harm to patients.
- **Increased Trust in Medical Devices:** Verification by the MDA provides assurance to healthcare providers and patients that the medical devices they use meet the highest standards of quality and safety.
- **Compliance with Regulatory Requirements**: Manufacturers and importers benefit from a clear and structured process for demonstrating compliance with Malaysian regulatory requirements, facilitating smoother market access.
- **Protection Against Substandard Products:** The verification process helps to prevent substandard or counterfeit medical devices from entering the market, safeguarding public health and maintaining industry integrity.

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.

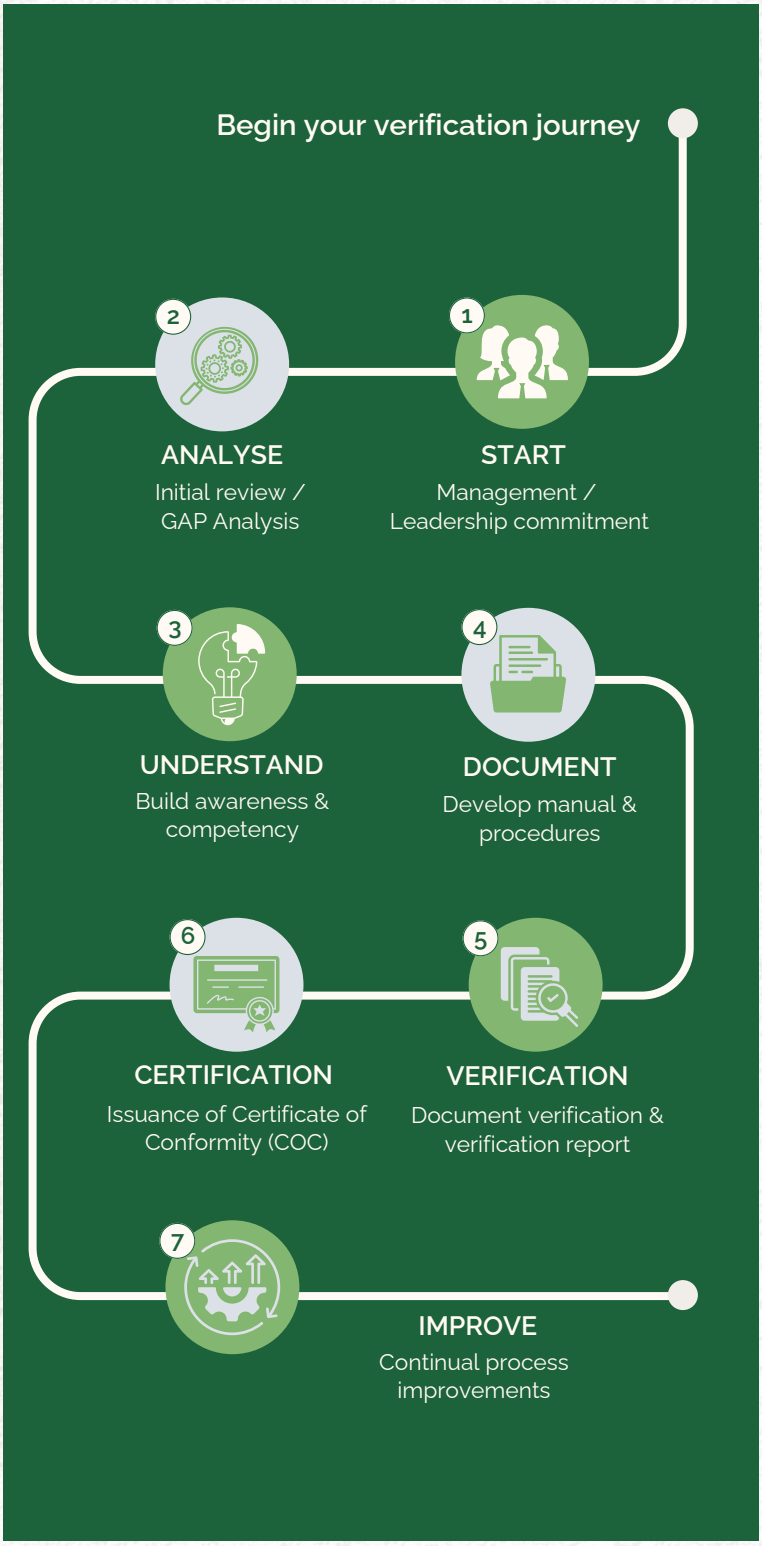
SUSTAINABLE DEVELOPMENT GOALS

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.



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

The implementation of the certifications offered by NIOSHCert are aligned with the United Nation's Sustainable Development Goals 2030.

Follow NIOSHCERTIFICATION