

GDPMD

GOOD DISTRIBUTION PRACTICE FOR MEDICAL DEVICES

ABOUT GDPMD

Good Distribution Practice for Medical Device (GDPMD) is made pursuant to Appendix 4 of Schedule 3 of the Medical Device Regulation 2012. GDPMD specifies the requirements for a quality management system to be established, implemented and maintained by an establishment in carrying out activities in medical device supply-chain to comply with Malaysian medical device regulatory requirements as stipulated in Medical Device Act 2012 (Act 737).

GDPMD requires an establishment to demonstrate its ability to maintain quality, safety and performance of medical devices in compliance with the Malaysian medical device regulatory requirement throughout the supply-chain. Distribution is an important activity in the integrated supply-chain of medical device. It involves various processes and activities such as product sourcing, procurement, transportation, delivery, storage, device tracking, installation, commissioning, service and maintenance, calibration, need to be appropriately managed and controlled to ensure the safety and performance of medical devices at the point of use. The level of risks associated with these activities may be of similar degree as those in the manufacturing environment and the lack of control over these activities may affect safety and performance of the devices.

The Good Distribution Practice for Medical Devices (GDPMD) is developed to clearly explain the requirements for an appropriate management and control of these activities.

BENEFITS

- Medical devices are appropriately managed and controlled throughout the supply chain. Thus, ensuring their safety and performance at the point of use.
- Assures stakeholders through certification that the organization can maintain quality, safety and performance of medical devices while under its custody.
- Fulfilment of establishment licensing requirements.



SUSTAINABLE DEVELOPMENT GOALS



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

