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Implementation of the Innovative Medical Device Review Pathway by Medical Device Authority, Ministry of Health Malaysia



Dear Valued Stakeholders,

Greetings from the Medical Device Authority (MDA).

We are pleased to announce the official launch of the Innovative Medical Device Pathway, a strategic initiative by MDA to support the

development and regulatory readiness of innovative medical devices in Malaysia.

This initiative is aligned with the objectives of the New Industrial Master Plan (NIMP) 2030, positioning MDA as a key enabler in fostering innovation through the collaboration between government, academia, and industry. The initiative offers regulatory advisory services, with a focus on the Essential Principles of Safety and Performance (EPSP), to assist innovators from early development stages through to market access, ensuring that novel devices are both clinically relevant and regulatorily compliant.

Currently, the pathway includes a sole, key initiative:

INITIATIVE 1:

Innovative Medical Devices Review Service – Provides regulatory advice on EPSP at different stages:

Early Development Review (TRL 3 – TRL 5):

Fee: RM 1,000 per session (2 hours)

Pre-commercial Review (TRL 6 – TRL 9):

Fee: RM 1,500 per session (2 hours)

We encourage all innovators, startups, and researchers to leverage this pathway to accelerate the development of safe, effective, and globally competitive medical devices.

Click [here](#) for more information

For more information, kindly contact us via [innovative-md](#)

Thank you.

Medical Device Authority (MDA)

Ministry of Health Malaysia



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