ANNOUNCEMENT UPDATE

Recognition of the Medical Device Authority (MDA) as an Affiliate Member of the Medical Device Single Audit Program (MDSAP) and Utilization of MDSAP Reports and Certificates

Dear All Medical Device Industry Stakeholders,

The Medical Device Authority (MDA) extends its highest regards to all valued stakeholders.

This announcement serves to inform the industry that the MDA has been **officially recognized as an Affiliate Membe**r of the **Medical Device Single Audit Program (MDSAP)** by the MDSAP Regulatory Authority Council (RAC) effective **16 September 2025**, following the recent official announcement published by MDA. This achievement marks an important milestone in strengthening Malaysia's medical device regulatory system by aligning with global best practices and greater reliance on internationally recognized audit programs.

With this recognition, MDA will begin accepting MDSAP reports and certificates to support regulatory submissions for establishment licensing and medical device registration as evidence of compliance with Quality Management System (QMS) requirements.

Implementation Scope

Application Type	Eligibility & Requirements
Establishment License Application	• **Local manufacturers** may utilize MDSAP reports and certificates as part of the required documentation for establishment license applications, in lieu of ISO 13485 certification. • The MDSAP audit shall be conducted by: 1) **A Conformity Assessment Body (CAB) registered with the MDA**; and 2) **An MDA-registered auditor qualified to perform MDSAP audits**.
Medical Device Registration Application	• **Local manufacturers** may utilize MDSAP reports and certificates under the same conditions as for establishment license applications. • **Foreign manufacturers** may utilize MDSAP reports and certificates issued by an MDSAP-recognized Auditing Organization as evidence of QMS compliance for the purpose of medical device registration in Malaysia.

This initiative aims to enhance regulatory efficiency, reduce duplication of audits, and facilitate faster market access while maintaining high standards of safety, quality, and performance for medical devices in Malaysia.

Thank you.

For further information and inquiries, please contact:

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