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ASIA EDITION

Malaysia, Thailand implement medical device reliance programme after successful pilot

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Significantly optimising the registration process for Class B, C, and D medical devices

The Medical Device Authority (MDA) of Malaysia and the Thai Food and Drug Administration (Thai FDA) of Thailand signed a Confidentiality Agreement to deepen regulatory cooperation and officially launched a 3-month pilot of the Medical Device Regulatory Reliance Programme as part of the agreement.

Following the successful completion of the three-month pilot phase (1 February 2026 to 30 April 2026), MDA and Thai FDA have announced the full implementation of the MDA – Thai FDA Medical Device Regulatory Reliance Programme for the registration of Class B, C, and D medical devices.

The pilot phase successfully demonstrated that the reliance model significantly optimises the registration process for Class B, C, and D medical devices by leveraging the regulatory reviews of a trusted partner. By utilising approval from MDA and Thai FDA, both authorities were able to reduce regulatory duplication, accelerate market access, and improve patient access to quality healthcare technologies. This streamlined approach provided a faster route to market while simultaneously ensuring safety, upholding rigorous performance standards through increased administrative efficiency.

The success of the initiative is further evidenced by the supportive participation of industry stakeholders in this pilot project, establishing a proof-of-concept for the reliance model and its future full implementation.

Effective immediately, the programme moves from a pilot status to full implementation of the MDA – Thai FDA Medical Device Regulatory Reliance Programme. This transition marks a permanent shift toward regulatory harmonisation between Malaysia and Thailand, streamlining the market entry process for medical device manufacturers in both territories.