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ASIA EDITION

Singapore sets global first by reaching WHO's highest classification for medical device regulation

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Singapore is a major global hub for medical technology innovation

The World Health Organization (WHO) has announced that Singapore's Health Sciences Authority (HSA) has achieved the highest level of regulatory performance for medical devices under WHO's global benchmarking framework.

Following a comprehensive assessment using WHO's Global Benchmarking Tool Plus for medical devices (GBT+MD), HSA reached maturity level 4 (ML4), the highest classification in WHO's system for national regulatory authorities overseeing medical products. Singapore is the first WHO Member State to attain this level for medical device regulation.

The designation confirms that Singapore's regulatory system operates at an advanced level of performance with mechanisms for continuous improvement, and consistently ensures the safety, quality and performance of medical devices throughout their life cycle, from market authorization and clinical evaluation to post-market surveillance.

Singapore is a major global hub for medical technology innovation, with around 200 manufacturers producing a wide range of devices, from in vitro diagnostics to software as a medical device.

HSA plays an active role in international regulatory harmonization, including participation in the International Medical Device Regulators Forum (IMDRF), the Medical Device Single Audit Program (MDSAP) and regional initiatives. As Chair of the IMDRF Management Committee in 2026, the regulatory authority is positioned to help advance global regulatory alignment for emerging technologies, such as digital health solutions, artificial intelligence and personalized medical devices.