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Wellthy Therapeutics announces expansion into US

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To revolutionise digital health worldwide with modular SaMD platform

Mumbai-based startup Wellthy Therapeutics, a global leader in digital health and digital therapeutics, has announced the successful completion of its FDA 21 CFR Part 820, FDA 21 CFR Part 11, and HIPAA certification for its disease-agnostic, modular, software-as-a-medical-device (SaMD) platform.

These international registrations further solidify the company's commitment to maintaining the highest standards of data security, data privacy, quality and regulatory compliance in the development and manufacturing of digital health solutions for customers in the United States, and worldwide, and reinforce its leadership in the SaMD space.

In addition to these recent certifications, the Wellthy Therapeutics platform is already compliant with EU MDR Class 1, ISO 13485, ISO 27001, ISO 27701, IEC 62304, and GDPR.

The platform simplifies the ability for pharma, HUBs, providers, and health plans to launch and scale globally compliant digital health and SaMD solutions. Clients leverage the platform to configure and commercialize their own customized digital health and SaMD solutions that are deployable in a matter of weeks and at a fraction of traditional costs, while addressing their specific business goals and complex patient needs. Over 150,000 patients have benefitted from Wellthy Therapeutics' platform so far, highlighting the value that the company's platform brings, and its continued leadership in the clinical outcomes and patient engagement space.