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ASIA EDITION

MiyaHealth obtains ISO Certification and a CE Mark for its Chronic Disease Management Platform

November 23, 2023 | News

One of the first Asia-based HealthTech to place software as a medical device on the EU market

MiyaHealth, a Singapore-headquartered global SaaS HealthTech, announced that it has secured ISO 13845:2016 certification and a CE Mark for *GensuApp*, its Chronic Disease Management Platform created in partnership with Bioton S.A., a Poland-based biotech company. In compliance with the European Union (EU) Medical Devices Regulatory Approval 2017/745, the CE Mark renders *GensuApp* as a Class 1 medical device, and allows MiyaHealth to place the product in Europe. Developed under MiyaHealth's proprietary product suite *MiyaPatient*, *GensuApp* focuses on diabetes management for patients, and it will be rolled out in Poland in the coming year.

Attaining the CE Mark for its Chronic Disease Management platform is a significant milestone for MiyaHealth as it demonstrates the company's technological capabilities and commitment to meeting the highest quality and safety standards expected of the healthcare industry. MiyaHealth is also one of the first Asia-based HealthTech companies to place software as a medical device in Europe. The CE Mark and ISO certification give MiyaHealth's partners the confidence and assurance that its products meet the General Safety and Performance Requirements (GSPR) of all relevant European medical device regulations, and are developed based on MiyaHealth's established Quality Management System.

Dr Ramesh Rajentheran, CEO and Co-Founder of MiyaHealth. "We are proud to share that we are one of the first Asia-based HealthTech companies to place software as a medical device in Europe, and we are grateful to Enterprise Singapore for supporting us in the development of *MiyaPatient* to help patients manage their chronic condition, as well as support healthcare providers in effective disease management."

GensuApp is developed under MiyaHealth's proprietary product suite, *MiyaPatient,* a patient navigation platform that includes an AI-driven, predictive and personalised system, *MiyaAvatar* to help them cope with their daily challenges. It proactively guides patients in chronic disease monitoring, medication, and care education and navigation. It is also compatible with a broad range of medical devices such as glucometers. The development of the proprietary technology and its viability validation was supported by Enterprise Singapore. MiyaHealth is also an investee of SEEDS Capital, its investment arm.

Globally, healthcare fragmentation and inequity have led to inefficiencies and high costs in healthcare services, and gaps in patient journeys when it comes to chronic disease management. Recognising these unmet needs, as well as the rising diabetes burden in Poland, MiyaHealth and Bioton S.A. partnered to develop *GensuApp*, a chronic disease management platform for diabetic patients. It was launched as a pilot initiative in 2022, and will be officially rolled out to Polish users.

Jeremy Launders, CEO at Bioton S.A. said “This partnership supports the course of our patient’s treatment and management of their conditions, ultimately leading to better outcomes. Managing diabetes can be challenging due to the numerous tasks required to achieve optimal glycaemic control. We have customised GensuApp with MiyaHealth to provide a comprehensive overview, offering patients and doctors real-time data to empower them to make better immediate decisions. Being the first of its kind in Poland, the GensuApp will allow us to support a wider network of people with diabetes. During our pilot programs, we have received excellent feedback from our patients.”

MiyaHealth plans to expand its *MiyaPatient suite* into potential markets of interest, and to onboard more partners, including insurers, hospitals, and government entities to develop tailored solutions that will scale up healthcare efficiency and access in these countries. In the coming months, MiyaHealth will be expanding its AI-driven interoperable digital healthcare solutions, *MiyaPayor* and *MiyaProvider*, into Indonesia and the Philippines. The company has successfully concluded their Pre-Series A fundraise in August this year and plans to raise Series A in 2024.