

SFDA Grants Marketing Authorization for AI-Powered Medical App to Measure Vital Signs

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The Saudi Food and Drug Authority (SFDA) has granted marketing authorization for an AI-powered digital medical application capable of measuring heart rate, oxygen saturation, and blood pressure via smartphone cameras.

With this approval, the SFDA becomes the first regulatory authority globally to grant marketing authorization for this application. The decision came after a comprehensive evaluation that reviewed technical documentation and clinical evidence to verify the application's safety and performance.

Utilizing Advanced Technology

The application employs remote photoplethysmography (rPPG) technology, utilizing advanced algorithms to analyze vital signs from a short facial video. To ensure accuracy, the application requires an initial blood pressure calibration using a certified medical device. It is not a standalone diagnostic tool and is not intended for emergency or critical care use.

From Regulatory Sandbox to Marketing Authorization

The launch of this application is a result of a fruitful collaboration between the SFDA and the Ministry of Health, represented by the Seha Virtual Hospital. Submitted by a specialized Canadian company, the application underwent testing and evaluation within the SFDA's Regulatory Sandbox. It then transitioned to the Authority's Innovative Medical Devices pathway, successfully completing all evaluation requirements, including a dedicated clinical trial conducted within Saudi Arabia.

Supporting Innovation and Health Transformation within the Year of AI

This decision embodies the SFDA's commitment to supporting digital health innovation and



ensuring the safe, regulated introduction of modern technologies to the Saudi market. It also underscores the Authority's ongoing efforts to foster innovation across the healthcare sector and promote modern medical technologies during the Year of AI 2026. This milestone reinforces the SFDA's role in adopting advanced technological solutions in line with the objectives of the Health Sector Transformation Program, a key pillar of Saudi Vision 2030.

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