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Japan's PHC receives first EU-MDR certification

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The In Vitro Diagnostics Division of PHC Corporation, a provider of medical devices and diagnostics, has received European Union Medical Devices Regulation (EU-MDR) certification for a motorized drug injection device that delivers anti-inflammatory medications called tumor-necrosis factor (TNF) inhibitors.

The device, called APP-1000, is designed to provide simple, precise, and monitored drug injections in the home setting for conditions including rheumatoid arthritis. The EU-MDR certification clears the way for future distribution of the device in approximately 20 countries including EU countries, Switzerland, and South America.

APP-1000 is a class IIa portable medical device, manufactured at PHC IVD's Wakimachi plant in Japan. It allows patients to self-inject TNF inhibitors automatically at a touch of a button with no measurement or preparation required. The device comes equipped with an LCD screen with illustrated guidance to make it easier for patients to use. Dosing history stored in the device memory can be transferred via Bluetooth to a smartphone, allowing patients and doctors to check the dosing record remotely at any time. In addition, patients can choose from three injection speeds depending on their needs.

This device is currently available in Japan. With the EU-MDR certification, PHC IVD plans to make it available in EU countries, Switzerland, and South America after June 2022.