



DEVICE DETAILS

NAME OF DEVICE	PULSE WAVE A-FIB PROMPT APP
ESTABLISHMENT NAME	HUAWEI TECHNOLOGIES (MALAYSIA) SDN BHD
ROLE OF ESTABLISHMENT	AUTHORIZED REPRESENTATIVE
REGISTRATION NO	GB7138225-216992
BRAND NAME	HUAWEI
MEDICAL DEVICE CATEGORY	MD 0100 - GENERAL NON-ACTIVE, NON-IMPLANTABLE MEDICAL DEVICES
DEVICE GROUPING TYPE	SINGLE
DEVICE DESCRIPTION	<p>The Pulse Wave A-fib Prompt App is an independent app that works with Huawei wearable devices. It analyzes pulse data to identify irregular heart rhythms and notifies users of suspected atrial fibrillation (A-fib). Users can actively collect data or enable automatic data collection in the background. When users choose to enable automatic data collection in the background, the app does not send a notification every time it detects suspected A-fib, so no notification does not mean that there is no irregularity. This data is only collected when the user is still. The app can be used to supplement the decision for A-fib screening. The app is not intended to diagnosis of atrial fibrillation. The app should not be used by anyone under the age of 18.</p>
DEVICE INTENDED PURPOSE	<p>The Pulse Wave A-fib Prompt App is an independent app that works with Huawei wearable devices. It analyzes pulse data to identify irregular heart rhythms and notifies users of suspected atrial fibrillation (A-fib). Users can actively collect data or enable automatic data collection in the background. When users choose to enable automatic data collection in the background, the app does not send a notification every time it detects suspected A-fib, so no notification does not mean that there is no irregularity. This data is only collected when the user is still. The app can be used to supplement the decision for A-fib screening. The app is not intended to diagnosis of atrial fibrillation. The app should not be used by anyone under the age of 18.</p>
VALIDITY DATE OF REGISTRATION	19/11/2025 - 18/11/2030

LIST OF DEVICE

NO	NAME OF DEVICE	IDENTIFIER
No results found.		