DEVICE DETAILS

NAME OF DEVICE	SAMSUNG ECG APP
ESTABLISHMENT NAME	SAMSUNG MALAYSIA ELECTRONICS (SME) SDN. BHD.
ROLE OF ESTABLISHMENT	AUTHORIZED REPRESENTATIVE
REGISTRATION NO	GB5340824-160419
BRAND NAME	SAMSUNG
MEDICAL DEVICE CATEGORY	MD 1300 - MONITORING DEVICES
DEVICE GROUPING TYPE	SINGLE
DEVICE DESCRIPTION	This is the ECG App consisting of ECG-Android (Phone app) and ECG-Tizen or ECG-Wear OS (Watch app). Operating System Software The ECG App (v1.1) is compatible with a Galaxy Watch Active2 with Tizen version 4.0.0.8 or above, or a later Watch model than the Galaxy Watch Active2 that is paired with a Galaxy phone running Android 9 or above. The ECG App (v1.2)* is compatible with a Galaxy Watch4 running Wear OS version 3.5 or above. The Galaxy Watch must be paired with a Samsung Galaxy smartphone running Android 9 or above. (* ECG App with IHRN feature)
DEVICE INTENDED PURPOSE	The Samsung's ECG App is an over-the-counter (OTC) software-only, mobile medical application operating on a compatible Samsung Galaxy Watch and Phone. The ECG App is intended to create, record, store, transfer, and display a single channel electrocardiogram (ECG), similar to a Lead I ECG for adults 22 years and older. Classifiable traces are labeled by the app as either atrial fibrillation (AFib) or sinus rhythm with the intention of aiding heart rhythm identification. In addition to the existing on-demand ECG function, the app also provide Irregular Heart Rhythm Notification (IHRN) feature which analyzes pulse rate data, on the background, to identify episodes of irregular heart rhythms suggestive of atrial fibrillation (AFib) and provides a notification suggesting the user record an ECG to analyze the heart rhythm. The IHRN Feature is not intended to provide a notification on every episode of irregular rhythm suggestive of AFib and the absence of a notification is not intended to indicate no disease process is present; rather the feature is intended to opportunistically acquire pulse rate data when the user is still and analyze the data when determined sufficient toward surfacing a notification.
VALIDITY DATE OF REGISTRATION	11/01/2024 - 10/01/2029

LIST OF DEVICE

NO	NAME OF DEVICE	IDENTIFIER
1	SAMSUNG ECG APP	ECG APP