



DEVICE DETAILS

NAME OF DEVICE	SAMSUNG ECG APP
ESTABLISHMENT NAME	SAMSUNG MALAYSIA ELECTRONICS (SME) SDN. BHD.
ROLE OF ESTABLISHMENT	AUTHORIZED REPRESENTATIVE
REGISTRATION NO	GB9718423-113876
BRAND NAME	SAMSUNG HEALTH MONITOR
MEDICAL DEVICE CATEGORY	MD 1111 - Software
DEVICE GROUPING TYPE	SINGLE
DEVICE DESCRIPTION	The Samsung ECG Application is an over-the-counter (OTC) software-only, mobile medical application operating on a compatible Samsung Galaxy Watch and Phone. The 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; it is not intended to replace traditional methods of diagnosis or treatment.
DEVICE INTENDED PURPOSE	The Samsung ECG App is an over-the-counter (OTC) software-only, mobile medical application operating on a compatible Samsung Galaxy Watch and Phone. The 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.
VALIDITY DATE OF REGISTRATION	01/01/2023 - 31/12/2027

LIST OF DEVICE

NO	NAME OF DEVICE	IDENTIFIER
1	SAMSUNG ECG APP	ECG APP