DEVICE DETAILS

NAME OF DEVICE	SAMSUNG BLOOD PRESSURE APP
ESTABLISHMENT NAME	SAMSUNG MALAYSIA ELECTRONICS (SME) SDN. BHD.
ROLE OF ESTABLISHMENT	AUTHORIZED REPRESENTATIVE
REGISTRATION NO	GB9228822-109076
BRAND NAME	SAMSUNG HEALTH MONITOR
MEDICAL DEVICE CATEGORY	MD 1111 - Software
DEVICE GROUPING TYPE	SINGLE
DEVICE DESCRIPTION	The Blood Pressure App (BP App) is a software-only, mobile medical application intended for use with a compatible Samsung Galaxy Watch and Phone to create, record, store and display blood pressure information. The BP App determines the systolic and diastolic blood pressure, as well as pulse rate, and provides values and history charts following calibration with a upper-arm, cuff- based blood pressure monitor. The BP App is intended for over-the-counter (OTC) use in adults 22 years and older.
DEVICE INTENDED PURPOSE	The Blood Pressure App (BP App) is a software-only, mobile medical application intended for use with a compatible Samsung Galaxy Watch and Phone to create, record, store and display blood pressure information. The BP App determines the systolic and diastolic blood pressure, as well as pulse rate, and provides values and history charts following calibration with an upper-arm, cuff-based blood pressure monitor. These data are only captured when the user is at rest. The BP App is intended for over-the-counter (OTC) use by adults 22 years and older. It may not provide accurate results for pregnant women. This information can be used as an indication for trends in blood pressure between regular checks by a healthcare professional. The user should not interpret or take clinical action based on the device output without consultation with a qualified healthcare professional and validation with a standard measurement method. The BP App is not intended to replace traditional methods for diagnosis or treatment of hypertension.
VALIDITY DATE OF REGISTRATION	15/11/2022 - 14/11/2027

LIST OF DEVICE

NO	NAME OF DEVICE	IDENTIFIER
1	SAMSUNG BLOOD PRESSURE APP	BP APP