



DEVICE DETAILS

NAME OF DEVICE	SAMSUNG SLEEP APNEA FEATURE
ESTABLISHMENT NAME	SAMSUNG MALAYSIA ELECTRONICS (SME) SDN. BHD.
ROLE OF ESTABLISHMENT	AUTHORIZED REPRESENTATIVE
REGISTRATION NO	GB4417025-208398
BRAND NAME	SAMSUNG HEALTH MONITOR
MEDICAL DEVICE CATEGORY	MD 1111 - Software
DEVICE GROUPING TYPE	SINGLE
DEVICE DESCRIPTION	The Sleep Apnea Feature is an over-the-counter (OTC) software-only, mobile medical application operating on a compatible Samsung Galaxy Watch and Phone.
DEVICE INTENDED PURPOSE	This feature is intended to detect signs of moderate to severe obstructive sleep apnea in the form of significant breathing disruptions over a two-night monitoring period, for adult users 22 years or older.
VALIDITY DATE OF REGISTRATION	31/07/2025 - 30/07/2030

LIST OF DEVICE

NO	NAME OF DEVICE	IDENTIFIER
1	SAMSUNG SLEEP APNEA FEATURE	SLEEP APNEA FEATURE