



DEVICE DETAILS

NAME OF DEVICE	SLEEP APNEA BREATHING THERAPY MASK (FULL FACE MASK) YUWELL
ESTABLISHMENT NAME	RAPHA MEDICAL SDN. BHD.
ROLE OF ESTABLISHMENT	AUTHORIZED REPRESENTATIVE
REGISTRATION NO	GB5130620-50431
BRAND NAME	YUWELL
MEDICAL DEVICE CATEGORY	MD 1100 - GENERAL ACTIVE MEDICAL DEVICES
DEVICE GROUPING TYPE	FAMILY
DEVICE DESCRIPTION	The mask is a noninvasive accessory used for channeling airflow (With or without supplemental oxygen) to a patient from a positive airway. • Pressure (PAP) device such as a continuous positive airway pressure (CPAP) or bi-level system. • The mask is to be used by patients (weighing>30kg), intended for single- patient reuse in the home environment. • The mask is intended for single-patient use in the hospital or institutional environment. Continuous positive airway pressure therapy (CPAP) uses a machine to help a person who has obstructive sleep apnea (OSA) breathe more easily during sleep. A CPAP machine increases air pressure in your throat so that your airway doesn't collapse when you breathe in.
DEVICE INTENDED PURPOSE	The mask is a noninvasive accessory used for channeling airflow (With or without supplemental oxygen) to a patient from a positive airway. • Pressure (PAP) device such as a continuous positive airway pressure (CPAP) or bi-level system. • The mask is to be used by patients (weighing>30kg), intended for single- patient reuse in the home environment. • The mask is intended for single-patient use in the hospital or institutional environment.
VALIDITY DATE OF REGISTRATION	07/12/2020 - 06/12/2025

LIST OF DEVICE

NO	NAME OF DEVICE	IDENTIFIER
1	Sleep Apnea Breathing Therapy Mask (Full Face Mask)	YF-01
2	Sleep Apnea Breathing Therapy Mask (Full Face Mask)	YF-02