



DEVICE DETAILS

NAME OF DEVICE	YUWELL SLEEP APNEA BREATHING THERAPY MASK (FULL FACE MASK)
ESTABLISHMENT NAME	RBD HEALTHCARE SDN BHD
ROLE OF ESTABLISHMENT	AUTHORIZED REPRESENTATIVE
REGISTRATION NO	GB7838322-113641
BRAND NAME	YUWELL
MEDICAL DEVICE CATEGORY	MD 0100 - GENERAL NON-ACTIVE, NON-IMPLANTABLE 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 bilevel 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.
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.
VALIDITY DATE OF REGISTRATION	23/12/2022 - 22/12/2027

LIST OF DEVICE

NO	NAME OF DEVICE	IDENTIFIER
1	SLEEP APNEA BREATHING THERAPY MASK	YF-01
2	SLEEP APNEA BREATHING THERAPY MASK	YF-02