



## DEVICE DETAILS

<b>NAME OF DEVICE</b>	YUWELL SLEEP APNEA BREATHING THERAPY MASK (FULL FACE MASK)
<b>ESTABLISHMENT NAME</b>	RBD HEALTHCARE SDN BHD
<b>ROLE OF ESTABLISHMENT</b>	AUTHORIZED REPRESENTATIVE
<b>REGISTRATION NO</b>	GB7838322-113641
<b>BRAND NAME</b>	YUWELL
<b>MEDICAL DEVICE CATEGORY</b>	MD 0100 - GENERAL NON-ACTIVE, NON-IMPLANTABLE MEDICAL DEVICES
<b>DEVICE GROUPING TYPE</b>	FAMILY
<b>DEVICE DESCRIPTION</b>	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.
<b>DEVICE INTENDED PURPOSE</b>	The mask is a noninvasive accessory used for channeling airflow (With or without supplemental oxygen) to a patient from a positive airway.
<b>VALIDITY DATE OF REGISTRATION</b>	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