



DEVICE DETAILS

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| 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 |
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| 1 | Sleep Apnea Breathing Therapy Mask (Full Face Mask) | YF-01 |
| 2 | Sleep Apnea Breathing Therapy Mask (Full Face Mask) | YF-02 |