



DEVICE DETAILS

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| NAME OF DEVICE | SILICONE FULLFACE MASK |
| ESTABLISHMENT NAME | BIOMETRIXS MEDITRONIXS GLOBAL |
| REGISTRATION NO | GB7350824-157213 |
| BRAND NAME | KNGMED |
| DEVICE GROUPING TYPE | FAMILY |
| DEVICE DESCRIPTION | KNGMED CPAP Full-face Masks is designed for the use of adult patients for the CPAP, Bi- PAP therapy prescribed by a healthcare professional or respiratory therapist. The KNGMED CPAP Full-face Masks are used with the CPAP, Bi-PAP, Auto-PAP therapy devices, ventilators and anesthesia devices for single patient or multi-patient use. This mask may not be suitable for persons with the following conditions: impaired cardiac sphincter function, excessive reflux, impaired cough reflex, and hiatal hernia. It should not be used if the patient is uncooperative, obtunded, unresponsive, or unable to remove the mask by themselves. The device consists of the following components; Frame/hub, Cushion, Forehead pad, Exhalation elbow, Exhalation port, Elbow swivel, Split washer, Forehead adjuster/bracket, Headgear clip, Headgear. It is typically made of plastic and/or silicone materials that create an airtight seal around the nose and mouth. It is available in various designs and sizes and stabilized with a head strap. It is a reusable device. |
| DEVICE INTENDED PURPOSE | The Full Face Mask channels airflow from ventilator/Positive Air Pressure(PAP) devices non-invasively to the patients who suffer from obstructive sleep apnea (OSA) or respiratory insufficiency and respiratory failure. The mask is to be used by adult patients (> 30 kg) requiring non-life-support ventilator assistance. |
| VALIDITY DATE OF REGISTRATION | 28/12/2023 - 27/12/2028 |

LIST OF DEVICE

| NO | NAME OF DEVICE | IDENTIFIER |
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| 1 | Silicone Fullface Masks | 7600040-S |
| 2 | Silicone Fullface Masks | 7600040-M |
| 3 | Silicone Fullface Masks | 7600040-L |
| 4 | Silicone Fullface Masks | 7600041-S |
| 5 | Silicone Fullface Masks | 7600041-M |
| 6 | Silicone Fullface Masks | 7600041-L |
| 7 | Silicone Fullface Masks | 7600042-S |

| NO | NAME OF DEVICE | IDENTIFIER |
|----|-------------------------|------------|
| 8 | Silicone Fullface Masks | 7600042-M |
| 9 | Silicone Fullface Masks | 7600042-L |

