



DEVICE DETAILS

NAME OF DEVICE	SILICONE FULLFACE MASK
ESTABLISHMENT NAME	BIOMETRIXS MEDITRONIXS GLOBAL
ROLE OF ESTABLISHMENT	AUTHORIZED REPRESENTATIVE
REGISTRATION NO	GB7350824-157213
BRAND NAME	KNGMED
MEDICAL DEVICE CATEGORY	MD 0101 - Non-active devices for anaesthesia, emergency and intensive care
DEVICE GROUPING TYPE	FAMILY
DEVICE DESCRIPTION	<p>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.</p>
DEVICE INTENDED PURPOSE	<p>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.</p>
VALIDITY DATE OF REGISTRATION	28/12/2023 - 27/12/2028

LIST OF DEVICE

NO	NAME OF DEVICE	IDENTIFIER
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

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

