



DEVICE DETAILS

NAME OF DEVICE	FULL FACE MASK
ESTABLISHMENT NAME	ROCKY SCIENTIFIC INSTRUMENTATION
ROLE OF ESTABLISHMENT	AUTHORIZED REPRESENTATIVE
REGISTRATION NO	GB8206826-222604
BRAND NAME	BMC
MEDICAL DEVICE CATEGORY	MD 1102 - Respiratory devices, including hyperbaric chambers for oxygen therapy, inhalation anaesthesia
DEVICE GROUPING TYPE	FAMILY
DEVICE DESCRIPTION	<p>Sleep dyspnea has become an unnegligible problem that trouble people every day. OSA and COPD are the common sleep dyspnea diseases, which has the greatest impact on society. Noninvasive positive-pressure ventilation (NPPV) successfully treats acute hypercapnic respiratory failure from exacerbation of chronic obstructive pulmonary disease (COPD). To achieve non-invasive positive airway pressure ventilation through a mask is still the most common method at present. The mask can be divided into Full face mask ,Nasal mask and Nasal pillows mask .The full face mask may be more effective because it eliminates mouth leaks, so the full face mask are widely accepted for less noise and more convenience. It is effective in delivery of non-invasive ventilation to patients. It may be advantageous in patients who are unable to tolerate the other kinds of masks. Mask covers patient's nose while the adjustable headgear straps hold the mask in place. Headgear Straps that are too loose permit air to leak while too tight traps can break the seal and create leaks; any strap pulled too tightly can cause discomfort. Headgear straps are snug enough for a good fit in all sleeping positions (side and front) but not tight. The straps loop into the hooks on the frame, and they both allow for quick, easy removal of the mask. F3 Full Face Masks have good safety performance and it is suitable for clinical, simple and safe operation.</p>
DEVICE INTENDED PURPOSE	<p>The mask is intended to provide an interface for patients who have been prescribed CPAP or bi-level therapy. The mask is • to be used by adult patients (> 66 lb / > 30 kg) requiring non-life-support ventilator assistance. • intended for single-patient use, for a maximum of seven days, in the hospital or institutional environment.</p>
VALIDITY DATE OF REGISTRATION	15/01/2026 - 14/01/2031

LIST OF DEVICE

NO	NAME OF DEVICE	IDENTIFIER
No results found.		