



DEVICE DETAILS

NAME OF DEVICE	FULL FACE MASK
ESTABLISHMENT NAME	ROCKY SCIENTIFIC INSTRUMENTATION
ROLE OF ESTABLISHMENT	AUTHORIZED REPRESENTATIVE
REGISTRATION NO	GB6254821-63660
BRAND NAME	BMC
MEDICAL DEVICE CATEGORY	MD 0101 - Non-active devices for anaesthesia, emergency and intensive care
DEVICE GROUPING TYPE	FAMILY
DEVICE DESCRIPTION	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.
DEVICE INTENDED PURPOSE	The F3 Full Face Mask channels airflow from ventilator systems 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. - The mask is intended for single-patient use, for a maximum of seven days, in the hospital or clinical environment.
VALIDITY DATE OF REGISTRATION	11/06/2021 - 10/06/2026

LIST OF DEVICE

NO	NAME OF DEVICE	IDENTIFIER
1	F3 Full Face Mask	10030523
2	F3 Full Face Mask	10030526
3	F3 Full Face Mask	10030529
4	F3 Full Face Mask	10030532
5	F3 Full Face Mask	10030522
6	F3 Full Face Mask	10030525
7	F3 Full Face Mask	10030528

NO	NAME OF DEVICE	IDENTIFIER
8	F3 Full Face Mask	10030531
9	F3 Full Face Mask	10030521
10	F3 Full Face Mask	10030524
11	F3 Full Face Mask	10030527
12	F3 Full Face Mask	10030530



MEDICAL DEVICE AUTHORITY