



DEVICE DETAILS

NAME OF DEVICE	NASAL MASK / NASAL PILLOWS INTERFACE / FULL FACE MASK
ESTABLISHMENT NAME	ROCKY SCIENTIFIC INSTRUMENTATION
ROLE OF ESTABLISHMENT	AUTHORIZED REPRESENTATIVE
REGISTRATION NO	GB10318220-46798
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.
DEVICE INTENDED PURPOSE	The Mask channels airflow non-invasively to a patient from a positive airway pressure device such as a continuous positive airway pressure (CPAP) or bi-level system. The Mask is: - to be used by adult patients (> 66 lb / 30 kg) for whom positive airway pressure therapy has been prescribed. - intended for single-patient re-use in the home environment and multi-patient re-use in the hospital / institutional environment.
VALIDITY DATE OF REGISTRATION	08/09/2020 - 07/09/2025

LIST OF DEVICE

NO	NAME OF DEVICE	IDENTIFIER
1	BMC-NM2 Nasal Mask	10020020
2	BMC-NM2 Nasal Mask	10020018
3	BMC-NM2 Nasal Mask	10020019
4	NM4 Nasal Mask	10020107
5	NM4 Nasal Mask	10020108
6	NM4 Nasal Mask	10020109
7	N5 Nasal Mask	10020180
8	N5 Nasal Mask	10020179
9	N5 Nasal Mask	10020178

NO	NAME OF DEVICE	IDENTIFIER
10	N5 Nasal Mask	10020334
11	N5A Nasal Mask	10020195
12	N5A Nasal Mask	10020194
13	N5A Nasal Mask	10020193
14	N5A Nasal Mask	10020335
15	P2 Nasal Pillows Interface	10010030
16	BMC-FM1A Full Face Mask	10030127
17	BMC-FM1A Full Face Mask	10030128
18	BMC-FM1A Full Face Mask	10030129
19	BMC-FM2 Full Face Mask	10030100
20	BMC-FM2 Full Face Mask	10030101
21	BMC-FM2 Full Face Mask	10030102
22	F1B Full Face Mask	10030163
23	F1B Full Face Mask	10030164
24	F1B Full Face Mask	10030165
25	F5 Full Face Mask	10030358
26	F5 Full Face Mask	10030357
27	F5 Full Face Mask	10030356
28	F5A Full Face Mask	10030324
29	F5A Full Face Mask	10030323
30	F5A Full Face Mask	10030322
31	N5H Nasal Mask	10020358
32	N5H Nasal Mask	10020359
33	N5H Nasal Mask	10020360
34	N5H Nasal Mask	10020361
35	N5AH Nasal Mask	10020370

NO	NAME OF DEVICE	IDENTIFIER
36	N5AH Nasal Mask	10020371
37	N5AH Nasal Mask	10020372
38	N5AH Nasal Mask	10020373
39	P2H Nasal Pillows Interface	10020391
40	Nasal Mask(N6)	10020662 S
41	Nasal Mask(N6)	10020663 M
42	Nasal Mask(N6)	10020664 L
43	Nasal Mask(N6)	10020660?All Size Kit?
44	Nasal Pillows Interface (P6)	10010069
45	Full Face Mask (F6)	10030754 S
46	Full Face Mask (F6)	10030753 M
47	Full Face Mask (F6)	10030752 L
48	Full Face Mask (F6)	10030756?All Size Kit?
49	Nasal Mask (N5+)	10020754 S
50	Nasal Mask (N5+)	10020753 M
51	Nasal Mask (N5+)	10020754 L
52	Nasal Mask (N5+)	10020756? All Size Kit?
53	Nasal Mask (N5A+)	10020635 S
54	Nasal Mask (N5A+)	10020634 M
55	Nasal Mask (N5A+)	10020633 L
56	Nasal Mask (N5A+)	10020636? All Size Kit?
57	Full Face Mask (F5+)	10030841 S
58	Full Face Mask (F5+)	10030840 M
59	Full Face Mask (F5+)	10030839 L
60	Full Face Mask (F5+)	10030842? All Size Kit?
61	Full Face Mask (F5A+)	10030849 S

NO	NAME OF DEVICE	IDENTIFIER
62	Full Face Mask (F5A+)	10030848 M
63	Full Face Mask (F5A+)	10030847 L
64	Full Face Mask (F5A+)	10030850?All Size Kit?
65	Nasal Mask(N5)	10020202?All Size Kit?
66	Nasal Mask(N5A)	10020273?All Size Kit?
67	Full Face Mask(F5)	10030371?All Size Kit?
68	Full Face Mask(F5A)	10030378?All Size Kit?

