



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	GB4432225-213093
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 negligible 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 Interface. The full-face mask may be more effective because it eliminates mouth leaks, so the full-face mask is 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. All type of Masks have good safety performance and it is suitable for clinical, simple and safe operation.</p>
DEVICE INTENDED PURPOSE	intended to provide an interface for patients who have been prescribed CPAP or bi-level therapy. The Mask is: <ul style="list-style-type: none"> • 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	02/10/2025 - 01/10/2030

LIST OF DEVICE

NO	NAME OF DEVICE	IDENTIFIER
1	BMC-NM2 Nasal Mask	06948538320006
2	BMC-NM2 Nasal Mask	06948538320013

NO	NAME OF DEVICE	IDENTIFIER
3	BMC-NM2 Nasal Mask	06948538320020
4	NM4 Nasal Mask	06948538360170
5	NM4 Nasal Mask	06948538360163
6	NM4 Nasal Mask	06948538360156
7	NM4 Nasal Mask	06948538360187
8	N5 Nasal Mask	06948538360439
9	N5 Nasal Mask	06948538360446
10	N5 Nasal Mask	06948538360453
11	N5 Nasal Mask	06948538360903
12	N5A Nasal Mask	06948538360460
13	N5A Nasal Mask	06948538360477
14	N5A Nasal Mask	06948538360484
15	N5A Nasal Mask	06948538360910
16	P2 Nasal Pillows Interface	06948538360194
17	BMC-FM1A Full Face Mask	06948538360026
18	BMC-FM1A Full Face Mask	06948538360019
19	BMC-FM1A Full Face Mask	06948538360002
20	BMC-FM2 Full Face Mask	06948538360088
21	BMC-FM2 Full Face Mask	06948538360071
22	BMC-FM2 Full Face Mask	06948538360064
23	F1B Full Face Mask	06948538360224
24	F1B Full Face Mask	06948538360217
25	F1B Full Face Mask	06948538360200
26	F5 Full Face Mask	06948538360514
27	F5 Full Face Mask	06948538360507
28	F5 Full Face Mask	06948538360491

NO	NAME OF DEVICE	IDENTIFIER
29	F5 Full Face Mask	06948538368381
30	F5 Full Face Mask	06948538368398
31	F5A Full Face Mask	06948538360545
32	F5A Full Face Mask	06948538360538
33	F5A Full Face Mask	06948538360521
34	F5A Full Face Mask	06948538368404
35	F5A Full Face Mask	06948538368411
36	N5H Nasal Mask	06948538360750
37	N5H Nasal Mask	06948538360767
38	N5H Nasal Mask	06948538360774
39	N5H Nasal Mask	06948538360873
40	N5H Nasal Mask	06948538360781
41	N5AH Nasal Mask	06948538360798
42	N5AH Nasal Mask	06948538360804
43	N5AH Nasal Mask	06948538360811
44	N5AH Nasal Mask	06948538360880
45	N5AH Nasal Mask	06948538360828
46	P2H Nasal Pillows Interface	06948538360743
47	Nasal Mask(N6)	06948538367469
48	Nasal Mask(N6)	06948538367452
49	Nasal Mask(N6)	06948538367445
50	Nasal Mask(N6)	06948538367476
51	Nasal Mask(N6)	06948538367490
52	Nasal Pillows Interface (P6)	06948538367483
53	Full Face Mask (F6)	06948538367186
54	Full Face Mask (F6)	06948538367179

NO	NAME OF DEVICE	IDENTIFIER
55	Full Face Mask (F6)	06948538367162
56	Full Face Mask (F6)	06948538367193
57	Full Face Mask (F6)	06948538368466
58	Full Face Mask (F6)	06948538367209
59	Nasal Mask (N5+)	06948538367230
60	Nasal Mask (N5+)	06948538367223
61	Nasal Mask (N5+)	06948538367216
62	Nasal Mask (N5+)	06948538367247
63	Nasal Mask (N5+)	06948538367254
64	Nasal Mask (N5A+)	06948538367285
65	Nasal Mask (N5A+)	06948538367278
66	Nasal Mask (N5A+)	06948538367261
67	Nasal Mask (N5A+)	06948538367292
68	Nasal Mask (N5A+)	06948538367308
69	Full Face Mask (F5+)	06948538367520
70	Full Face Mask (F5+)	06948538367513
71	Full Face Mask (F5+)	06948538367506
72	Full Face Mask (F5+)	06948538368428
73	Full Face Mask (F5+)	06948538368435
74	Full Face Mask (F5+)	06948538367537
75	Full Face Mask (F5A+)	06948538367568
76	Full Face Mask (F5A+)	06948538367551
77	Full Face Mask (F5A+)	06948538367544
78	Full Face Mask (F5A+)	06948538368442
79	Full Face Mask (F5A+)	06948538368459
80	Full Face Mask (F5A+)	06948538367575

NO	NAME OF DEVICE	IDENTIFIER
81	Nasal Mask(N5)	06948538360552
82	Nasal Mask(N5A)	06948538360637
83	Full Face Mask(F5)	06948538360729
84	Full Face Mask(F5A)	06948538360736
85	Full Face Mask (F6S)	06948538368145
86	Full Face Mask (F6S)	06948538368138
87	Full Face Mask (F6S)	06948538368121
88	Full Face Mask (F6S)	06948538368152
89	Full Face Mask (F6S)	06948538368169
90	Nasal Mask(N6S)	06948538367964
91	Nasal Mask(N6S)	06948538367957
92	Nasal Mask(N6S)	06948538367940
93	Nasal Mask(N6S)	06948538368336
94	Nasal Mask(N6S)	06948538367971
95	Nasal Pillows Interface (P6S)	06948538368015



MEDICAL DEVICE AUTHORITY