



DEVICE DETAILS

NAME OF DEVICE	RESPIRATORY FACE MASKS (BITRAC NIC SELECT, BITRAC SHIELD, MAXSHIELD MASKS & ACCESSORIES) (LIST OF MEDICAL DEVICE AS LISTED IN ANNEX I)
ESTABLISHMENT NAME	GOODLABS MEDICAL (M) SDN BHD
REGISTRATION NO	GB2839720-38836
BRAND NAME	PULMODYNE
DEVICE GROUPING TYPE	FAMILY
DEVICE DESCRIPTION	Respiratory Face Masks are intended for single patient use and are provided clean, non-sterile. The face mask family comes in a variety of sizes and styles to meet user preference. In addition to offering different sizes and cushion styles of masks, we also include headgear, and forehead pads. The masks provide a seal so that positive pressure from a positive pressure source is directed to the patient's face/nasal area. It is held in place with an adjustable headgear system.
DEVICE INTENDED PURPOSE	The BiTrac Full Face mask is an accessory for use with CPAP or Bilevel systems used in the treatment of adult Obstructive Sleep Apnea (OSA) and/or ventilator support
VALIDITY DATE OF REGISTRATION	28/11/2019 - 27/11/2024

LIST OF DEVICE



NO	NAME OF DEVICE	IDENTIFIER
1	BiTrac Select Full Face Mask	313?9543
2	BiTrac Select Full Face Mask	313?9542
3	BiTrac Select Full Face Mask	313?9541
4	BiTrac Select Full Face Mask	313?9548
5	BiTrac Select Full Face Mask	313?9547
6	BiTrac Select Full Face Mask	313?9546
7	BiTrac Select Full Face Mask	313?9048W
8	BiTrac Select Full Face Mask	313?9047W
9	BiTrac Select Full Face Mask	313?9046W
10	BiTrac Select Full Face Mask	313?9044W
11	BiTrac Select Full Face Mask	313?9043W

NO	NAME OF DEVICE	IDENTIFIER
12	BiTrac Select Full Face Mask	313?9042W
13	BiTrac Select Full Face Mask	313?9573
14	BiTrac Select Full Face Mask	313?9572
15	BiTrac Select Full Face Mask	313?9571
16	BiTrac Select Nasal Mask	313?9049W
17	BiTrac Select Nasal Mask	313?9041W
18	BiTrac Select Nasal Mask	313?9040W
19	BiTrac Select MaxShield Mask	313?9555
20	BiTrac Select MaxShield Mask	313?9556
21	BiTrac Select MaxShield Mask	313?9552
22	BiTrac Select MaxShield Mask	313?9554
23	BiTrac Select MaxShield Mask	313?9553
24	BiTrac Select MaxShield Mask	313?9551
25	BiTrac MaxShield Mask	313?9052W
26	BiTrac MaxShield Mask	313?9054W
27	BiTrac MaxShield Mask	313?9053W
28	BiTrac MaxShield Mask	313?9055W
29	BiTrac Shield Mask	313?9050W
30	BiTrac Shield Mask	313?9051W
31	BiTrac Select MaxShield Mask	313?9526
32	BiTrac Select MaxShield Mask	313?9527
33	BiTrac Select MaxShield Mask	313?9524
34	BiTrac Select MaxShield Mask	313?9525
35	BiTrac SE Select Interchangeable Standard Elbow	313?9599
36	BiTrac Select Interchangeable Anti? Asphyxia Elbow	313?9598
37	BiTrac SE Select Interchangeable Standard Bronchoscopy Elbow	313?9597

NO	NAME OF DEVICE	IDENTIFIER
38	BiTrac Select Interchangeable Anti? Asphyxia Bronchoscopy Elbow	313?9596
39	BiTrac SE Select Interchangeable Nebulizer Elbow	313?9595
40	BiTrac Select Interchangeable Anti? Asphyxia Nebulizer Elbow	313?9594
41	BiTrac Select Interchangeable Anti? Asphyxia w/Leak Elbow Size	313?9593
42	BiTrac SE Select Pediatric Standard Elbow	313?9601
43	BiTrac Select Pediatric Anti? Asphyxia w/Leak Elbow	313?9602
44	BiTrac Select Interchangeable Anti? Asphyxia w/Leak Elbow Size	313?9593?A

