





DEVICE DETAILS

NAME OF DEVICE	PULSE OXIMETER SAT 805
ESTABLISHMENT NAME	AL GLOBAL CORPORATION (M) SDN BHD
ROLE OF ESTABLISHMENT	AUTHORIZED REPRESENTATIVE
REGISTRATION NO	GC762641231018
BRAND NAME	BITMOS
MEDICAL DEVICE CATEGORY	MD 1302 - Monitoring devices of vital physiological parameters
DEVICE GROUPING TYPE	SYSTEM
DEVICE DESCRIPTION	PULSE OXIMETRY IS A NONINVASIVE AND PAINLESS TEST THAT MEASURES YOUR OXYGEN SATURATION LEVEL, OR THE OXYGEN LEVELS IN YOUR BLOOD. IT CAN RAPIDLY DETECT EVEN SMALL CHANGES IN HOW EFFICIENTLY OXYGEN IS BEING CARRIED TO THE EXTREMITIES FURTHEST FROM THE HEART, INCLUDING THE LEGS AND THE ARMS. THE PULSE OXIMETER IS A SMALL, CLIP-LIKE DEVICE THAT ATTACHES TO A BODY PART, LIKE TOES OR AN EARLOBE. IT'S MOST COMMONLY PUT ON A FINGER, AND IT'S OFTEN USED IN A CRITICAL CARE SETTING LIKE EMERGENCY ROOMS OR HOSPITALS. SOME DOCTORS, SUCH AS PULMONOLOGISTS, MAY USE IT IN OFFICE
DEVICE INTENDED PURPOSE	THE DEVICE IS SUITABLE FOR ADULTS, CHILDREN AND NEWBORNS. SUITABILITY IS DUE TO THE AVAILABLE SENSORS THAT ALLOW MONITORING. FOR THIS PURPOSE, A DISTINCTION BASED ON WEIGHT CLASSES AND APPLICATION SITES IS FORMED
VALIDITY DATE OF REGISTRATION	20/12/2018 - 19/12/2023

LIST OF DEVICE

NO	NAME OF DEVICE	IDENTIFIER
1	Pulse Oximetry	SAT 805
2	Accessories	16-4000
3	Accessories	16-4001
4	Accessories	16-4003
5	Accessories	16-4002
6	Accessories	16-4004
7	Accessories	16-4050
8	Accessories	16-4051

NO	NAME OF DEVICE	IDENTIFIER
9	Accessories	16-4080
10	Accessories	16-4108
11	Accessories	16-4081
12	Accessories	16-4088
13	Accessories	16-4105
14	Accessories	2514
15	Accessories	2329
16	Accessories	4072
17	Accessories	4090
18	Accessories	3934
19	Accessories	3343
20	Accessories	3375
21	Accessories 	2308
22	Accessories	2508
23	Accessories	2509
24	Accessories	2510
25	Accessories	2511
26	Accessories	2696
27	Accessories	2697
28	Accessories	2406
29	Accessories	2404
30	Accessories	4071
31	Accessories	4072
32	Accessories	4073
33	Accessories	2056
34	Accessories	2510

NO	NAME OF DEVICE	IDENTIFIER
35	Accessories	2501
36	Accessories	2502
37	Accessories	2505
38	Accessories	2525
39	Accessories	3985
40	Accessories	2060
41	Accessories	2053
42	Accessories	16-1396
43	Accessories	16-1969
44	Accessories	16-1859
45	Accessories	16-2329
46	Accessories	16-2320
47	Accessories 	16-1860
48	Accessories	16-2330
49	Accessories	16-2321
50	Accessories	16-2328
51	Accessories	16-2319
52	Accessories	16-1863
53	Accessories	16-1864
54	Accessories	16-1895
55	Accessories	16-2258
56	Accessories	16-2653
57	Accessories	16-2364
58	Accessories	16-2017
59	Accessories	16-1814
60	Accessories	16-2013

NO	NAME OF DEVICE	IDENTIFIER
61	Accessories	16-4046
62	Accessories	16-4047
63	Accessories	16-4048
64	Accessories	16-1597
65	Accessories	16-1598
66	Accessories	16-1602

