



DEVICE DETAILS

NAME OF DEVICE	MASIMO PULSE OXIMETER SENSORS
ESTABLISHMENT NAME	NYPRAX BUSINESS SOLUTIONS
ROLE OF ESTABLISHMENT	AUTHORIZED REPRESENTATIVE
REGISTRATION NO	GC484561060118
BRAND NAME	MASIMO
MEDICAL DEVICE CATEGORY	MD 1302 - Monitoring devices of vital physiological parameters
DEVICE GROUPING TYPE	FAMILY
DEVICE DESCRIPTION	<p>MASIMO SET SENSORS: THE SERIES OF SENSORS ARE MULTI-WAVELENGTH SENSORS USED TO DISTINGUISH BETWEEN OXYGENATED BLOOD, DEOXYGENATED BLOOD, BLOOD WITH CARBON MONOXIDE, AND BLOOD WITH OXIDIZED HEMOGLOBIN. SIGNAL DATA IS OBTAINED BY PASSING VARIOUS VISIBLE AND INFRARED LIGHTS (7+ LIGHT-EMITTING DIODES (LED%U2019S)) THROUGH A CAPILLARY BED (FOR EXAMPLE, A FINGERTIP, A HAND, A FOOT) AND MEASURING CHANGES IN LIGHT ABSORPTION DURING THE BLOOD PULSATILE CYCLE. THE PHOTODETECTOR RECEIVES THE LIGHT, CONVERTS IT INTO AN ELECTRONIC SIGNAL AND SENDS IT TO THE INSTRUMENT FOR CALCULATION AND DISPLAY OF FUNCTIONAL OXYGEN SATURATION (SPO₂), PULSE RATE, FRACTIONAL CONCENTRATIONS OF CARBOXYHEMOGLOBIN (SPCO), METHEMOGLOBIN (SPMET), AND/OR TOTAL HEMOGLOBIN (SPHB), AND/OR FRACTIONAL OXYGEN SATURATION* (SPFO₂). THE RAINBOW SERIES OF SENSORS (AND CABLES) ARE INDICATED FOR SPOT-CHECKING AND/OR CONTINUOUS NONINVASIVE MONITORING OF FUNCTIONAL/ARTERIAL OXYGEN SATURATION (SPO₂), CARBOXYHEMOGLOBIN SATURATION (SPCO), METHEMOGLOBIN SATURATION OF ARTERIAL HEMOGLOBIN (SPMET), AND/ OR TOTAL HEMOGLOBIN CONCENTRATION (SPHB), AND/OR FRACTIONAL OXYGEN SATURATION (SPFO₂), AND OXYGEN CONTENT, AND PULSE RATE, FOR ADULT, PEDIATRIC, INFANT, AND/ OR NEONATAL PATIENTS IN HOSPITALS, HOSPITAL-TYPE FACILITIES, MOBILE, AND HOME ENVIRONMENTS. MASIMO SET SENSORS: THE M-LNCS SERIES OF SPO₂ PULSE OXIMETRY SENSORS MEASURE THE LIGHT ABSORPTION OF BLOOD FROM TWO LIGHT EMITTING DIODES (LED%U2019S). OXYGEN SATURATED BLOOD ABSORBS LIGHT DIFFERENTLY AS COMPARED TO UNSATURATED BLOOD. THE AMOUNT OF LIGHT ABSORBED BY THE BLOOD IS USED TO CALCULATE THE RATIO OF OXYGENATED HEMOGLOBIN TO TOTAL HEMOGLOBIN IN ARTERIAL BLOOD.</p>
DEVICE INTENDED PURPOSE	<p>THE SENSORS ARE INDICATED FOR THE CONTINUOUS NON-INVASIVE MONITORING OF ARTERIAL SATURATION (SPO₂), ARTERIAL CARBOXYHEMOGLOBIN SATURATION (SPCO&reg;), ARTERIAL METHEMOGLOBIN SATURATION (SPMET&reg;) AND PULSE RATE. THE SENSORS ARE FOR USE WITH INSTRUMENTS CONTAINING MASIMO TECHNOLOGY OR LICENSED TO USE COMPATIBLE SENSORS.</p>

LIST OF DEVICE

NO	NAME OF DEVICE	IDENTIFIER
1	Rainbow R1 25	3792
2	rainbow R1 20	3793
3	rainbow R1 25L	2414
4	rainbow R1 20L	2415
5	rainbow R25	2221
6	rainbow R20	2222
7	rainbow R25-L	2219
8	rainbow R20-L	2220
9	LNCS Amtx	1859
10	LNCS Amtx-3	2317
11	LNCS E1	2918
12	LNCS TFA-1	2858
13	LNCS Red TFA-1	3857
14	LNCS Pmtx	1860
15	LNCS Pmtx-3	2318
16	LNCS Inf-L	1861
17	LNCS Neo-L	1862
18	LNCS NeoPt-L	1901
19	LNCS Inf	2328
20	LNCS Inf-3	2319
21	LNCS Neo	2329
22	LNCS Neo-3	2320



MEDICAL DEVICE AUTHORITY

NO	NAME OF DEVICE	IDENTIFIER
23	LNCS NeoPt	2330
24	LNCS NeoPt-3	2321
25	LNCS NeoPt-500	2331
26	LNCS Trauma	2411
27	LNCS Newborn Neonatal	2412
28	LNCS Newborn Infant / Pediatrics	2413
29	M-LNCS Amtx	2508
30	M-LNCS Amtx-3	2509
31	M-LNCS Pmtx	2510
32	M-LNCS Pmtx-3	2511
33	M-LNCS E1	2919
34	M-LNCS TFA-1	3856
35	M-LNCS Red TFA-1	3855
36	M-LNCS Inf-L	3670
37	M-LNCS Neo-L	3668
38	M-LNCS NeoPt-L	3669
39	M-LNCS Inf	2512
40	M-LNCS Inf-3	2513
41	M-LNCS Neo	2514
42	M-LNCS Neo-3	2515
43	M-LNCS NeoPt	2516
44	M-LNCS NeoPt-3	2517
45	M-LNCS NeoPt-500	2518
46	M-LNCS Trauma	2521
47	M-LNCS Newborn Neonatal	2519
48	M-LNCS Newborn Infant/Pediatric	2520



MEDICAL DEVICE AUTHORITY

NO	NAME OF DEVICE	IDENTIFIER
49	M-LNCS Blue	2522
50	LNOP Adt	1001
51	LNOP Pdt	1025
52	LNOP Inf-L	1800
53	LNOP Neo-L	1798
54	LNOP NeoPt-L	1651
55	LNOP Trauma	2358
56	LNOP Newborn Neonatal	2203
57	LNOP Newborn Infant/Pediatric	2204
58	LNOP Blue	1970
59	RD SET Adt	4000
60	RD SET Pdt	4001
61	RD SET Inf	4002
62	RD SET Neo	4003
63	RD SET NeoPt	4004
64	RD SET NeoPt-500	4005
65	RD SET Trauma	4011
66	RD SET Newborn Neonatal	4013
67	RD SET Newborn I/P	4012
68	RD Rainbow SET-2 Adt	4026
69	RD Rainbow SET-2 Pdt	4027
70	RD Rainbow SET-2 Inf	4028
71	RD Rainbow SET-2 Neo	4029
72	RD Rainbow SET-3 Adt	4030
73	RD Rainbow SET-3 Pdt	4031
74	RD Rainbow SET-3 Inf	4032



MEDICAL DEVICE AUTHORITY

NO	NAME OF DEVICE	IDENTIFIER
75	RD Rainbow SET-3 Neo	4033
76	RD Rainbow Lite SET-1 Adt	4042
77	RD Rainbow Lite SET-1 Paed	4043
78	RD Rainbow Lite SET-1 Inf	4044
79	RD Rainbow Lite SET-1 Neo	4045
80	Ras-45, Acoustic Respiration	4171
81	RD SedLine Sensor	4248
82	rainbow ReSposable R2-25 Sensor System	3457
83	rainbow ReSposable R2-20 Sensor System	3458
84	rainbow ReSposable R2-25r Sensors	3395
85	rainbow ReSposable R2-20r Sensors	3411
86	rainbow ReSposable™R2-25a Sensors	2753
87	rainbow ReSposable™ R2-20a Sensors	2755
88	rainbow DCI SC 200	3418
89	rainbow DCIP SC 200	3419
90	rainbow DCI SC 400	3420
91	rainbow DCIP SC 400	3421
92	rainbow DCI SC 1000	3647
93	rainbow DCIP SC 1000	3648
94	rainbow DCI-mini SC 200	3797
95	rainbow DCI-mini SC 400	3798
96	rainbow DCI-mini SC 1000	3799
97	rainbow 4D DC Sensor, Small	9400
98	rainbow 4D DC Sensor, Medium	9401
99	rainbow 4D DC Sensor, Large	9402
100	rainbow DCI	2696

NO	NAME OF DEVICE	IDENTIFIER
101	rainbow DCIP	2697
102	rainbow DCI-6	3657
103	rainbow DCIP-6	3658
104	rainbow DCI-dc3	2201
105	rainbow DCIP-dc3	2069
106	LNCS DCI	1863
107	LNCS DCIP	1864
108	LNCS DBI	2853
109	LNCS TC-I	1895
110	LNCS Y-I	2258
111	LNCS TF-I	1896
112	M-LNCS DCI	2501
113	M-LNCS DCIP	2502
114	M-LNCS DBI	2507
115	M-LNCS TC-I	2503
116	M-LNCS Y-I	2505
117	M-LNCS TF-I	2504
118	LNOP DCI	1269
119	LNOP DCIP	1276
120	LNOP TC-I	1794
121	LNOP TF-I	1793
122	LNOP DC-195	1560
123	LNOP Y-I	1544
124	DCSC	1396
125	DB-I-dc3	2651
126	Red DCI-dc3	2053



MEDICAL DEVICE AUTHORITY

NO	NAME OF DEVICE	IDENTIFIER
127	Red DCIP-dc3	2256
128	Red DBI-dc3	2643
129	LNCS DBI SpO2	2653
130	RD SET DCI	4050
131	RD SET DCI-P	4051
132	RD SET YI	4054
133	Rainbow Super DCI-mini Lite SC 200	4309
134	Rainbow Super DCI-mini Lite SC 400	4310
135	Rainbow Super DCI-mini Lite SC 1000	4311
136	RD SET Tip Clip	4053
137	RD SET TFA-1 Adult / Pediatric SpO2 disposable tranflectance forehead sensor, 3 ft	4016
138	RD SET Blue Neonatal / Infant / Pediatric SpO2 Adhesive Sensor	4014
139	RD SET E1 Adult SpO2, Disposable Ear Sensor, 3ft	4015
140	RD SET DBI Adult Soft Reusable Sensor, 3ft	4052
141	RD SET Adt CS-2 Adult SpO2 Adhesive Sensor, 2ft	4470
142	RD SET Pft CS-2 Pediatric SpO2 Adhesive Sensor, 2ft	4471
143	RD SET Inf CS-2 Infant SpO2 Adhesive Sensor, 2ft	4472
144	RD SET Neo CS-2 Adult / Neonatal SpO2 Adhesive Sensor, 2ft	4473
145	RD SET NeoPt CS-2 Neonatal SpO2 Adhesive Sensor, 2ft	4474
146	RD SET Adt CS-3 Adult SpO2 Adhesive Sensor, 3ft	4475
147	RD SET Pdt CS-3 Pediatric SpO2 Adhesive Sensor, 3ft	4476
148	RD SET Neo CS-3 Adult / Neonatal SpO2 Adhesive Sensor, 3ft	4477
149	RD SET Neo CS-3 Adult / Neonatal SpO2 Adhesive Sensor, 3ft	4478
150	RD SET NeoPt CS-3 Neonatal SpO2 Adhesive Sensor, 3ft	4479
151	RD SET™ TF-1	4055
152	RD SedLine EEG Sensor, Adult	4248

NO	NAME OF DEVICE	IDENTIFIER
153	RD SedLine EEG Sensor, Pediatric	4329
154	Rainbow DCIP-dc12, Pediatric Reusable, 12 ft. 1/box, (SpO2, SpCO, SpMet)	2070
155	Rainbow DCI-dc12, Adult Reusable Direct Connect Sensor, 12 ft, 1/box (SpO2, SpCO, SpMet)	2202
156	Rainbow DC-3 SC-360, Adult Reusable Sensor, 3 ft, 1/box (SpO2, SpHb), 360 Spot checks	2241
157	Rainbow DC-12 SC-360, Adult Reusable Sensor, 12 ft, 1/box (SpO2, SpHb), 360 Spot checks	2242
158	Rainbow Adult Sample Pack, 1-Rainbow R25 and 1-Rainbow R25-L Sensor SpO2, SpCO, SpMet Sensors	2291
159	Rainbow Ped/Inf Sample Pack, 1 Rainbow R20 and 1 Rainbow R20-L Sensor SpO2, SpCO, SpMet Sensors	2292
160	Rainbow DCI SC-360, Adult Reusable Sensor, 3 ft, 1/box (SpO2, SpHb), 360 Spot checks	2333
161	Rainbow DCIP SC-360, Pediatric Reusable Sensor, 3 ft, 1/box (SpO2, SpHb), 360 Spot checks	2334
162	Rainbow DCP-3 SC-360, Pediatric Reusable Sensor, 3 ft. 1/box, (SpO2, SpHb), 360 Spot checks	2402
163	Rainbow DCP-12 SC-360, Pediatric Reusable Sensor, 12 ft. 1/box, (SpO2, SpHb), 360 Spot checks	2403
164	Rainbow DCI-dc8, Adult Reusable Direct Connect Sensor, 8 ft, 1/box (SpO2, SpCO, SpMet)	2407
165	Rainbow R1 25, Adult Adhesive Sensors (SpO2, SpHb, SpMet), 10/box	2416
166	Rainbow R1 20, Pediatric Adhesive Sensors (SpO2, SpHb, SpMet), 10/box	2417
167	Rainbow R1 25 Adult Demo Pack, 2 Rainbow R1 25 SpHb, SpO2, SpMet Sensors	2625
168	Rainbow R1 20 Ped Demo Pack, 2 Rainbow R1 20 SpHb, SpO2, SpMet Sensors	2626
169	Rainbow DCIP-dc8, Pediatric Reusable, 8ft, 1/box (SpO2, SpCO, SpMet)	2640
170	Rainbow DC-3 SC-200, Adult Reusable Sensor, 3 ft, 1/box (SpO2, SpHb), 200 Spot checks	2646
171	Rainbow DCP-3 SC-200, Pediatric Reusable Sensor, 3 ft, 1/box (SpO2, SpHb), 200 Spot checks	2647

NO	NAME OF DEVICE	IDENTIFIER
172	Rainbow R1 25L Adult Demo Pack, 2 Rainbow R1 25L SpHb, SpO2, SpMet Sensors	2745
173	Rainbow R1 20L Inf Demo Pack, 2 Rainbow R1 20L SpHb, SpO2, SpMet Sensors	2746
174	Rainbow ReSposable R2-25r, Adult Reusable Sensors, SpO2, SpHb & SpMet (5/box)	2754
175	Rainbow ReSposable R2-20r, Pediatric Reusable Sensors, SpO2, SpHb & SpMet (5/box)	2756
176	Rainbow 4D DC SC-500, 500 Spot Check Sensor, SpHb, SpO2, PR, PI	2953
177	Rainbow 4D DC SC-1000, 1000 Spot Check Sensor, SpHb, SpO2, PR, PI	2954
178	RAS-45 Inf/Neo, Acoustic Respiration Sensor, 3ft	4425
179	SpO2.com A, Adult Adhesive Sensors, 24/Box	1774
180	SpO2.com P, Pediatric Adhesive Sensors, 24/Box	1775
181	SpO2.com, Infant Adhesive Sensors, 24/Box	1777
182	SpO2.com, Neonatal Adhesive Sensors, 24/Box	1176
183	RD rainbow Adt 8λ SpCO	4034
184	RD rainbow Pdt 8λ SpCO	4035
185	RD rainbow Inf 8λ SpCO	4036
186	RD rainbow Neo 8λ SpCO	4037
187	LNCS-II rainbow DCI 8λ SpCO	4067
188	LNCS-II rainbow DCIP 8λ SpCO	4068
189	LNCS-II rainbow DCI-6 8λ SpCO Adt	4069
190	LNCS-II rainbow DCIP-6 8λ SpCO Pdt	4070
191	LNCS-II rainbow DCI 8λ SpHb, SC 200	4058
192	LNCS-II rainbow DCIP 8λ SpHb, SC 200	4061
193	LNCS-II rainbow DCI 8λ SpHb SC 400	4059
194	LNCS-II rainbow DCIP 8λ SpHb SC 400	4062
195	LNCS-II rainbow DCI 8λ SpHb, SC 1000	4060

NO	NAME OF DEVICE	IDENTIFIER
196	LNCS-II rainbow DCIP 8λ SpHb, SC 1000	4063
197	RD SET Adt CS-1	4615
198	RD SET Neo CS-1	4886
199	RD rainbow Adt 12λ SpHb SpCO	4038
200	RD rainbow Pdt 12λ SpHb SpCO	4039
201	RD rainbow Inf 12λ SpHb SpCO	4040
202	RD rainbow Neo 12λ SpHb SpCO	4041



MEDICAL DEVICE AUTHORITY