



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>

**VALIDITY DATE OF
REGISTRATION**

29/06/2018 - 28/06/2023

LIST OF DEVICE

NO	NAME OF DEVICE	IDENTIFIER
1	RAS-125, Acoustic Respiration Sensor	2759
2	RAS-125c, Acoustic Respiration Cloth Sensor	3475
3	RAS-125c, Short Term Monitoring Acoustic Respiration Cloth Sensor	3483
4	Rainbow R1 25	3792
5	rainbow R1 20	3793
6	rainbow R1 25L	2414
7	rainbow R1 20L	2415
8	rainbow R25	2221
9	rainbow R20	2222
10	rainbow R25-L	2219
11	rainbow R20-L	2220
12	LNCS Amtx	1859
13	LNCS Amtx-3	2317
14	LNCS E1	2918
15	LNCS TFA-1	2858
16	LNCS Red TFA-1	3857
17	LNCS Pmtx	1860
18	LNCS Pmtx-3	2318
19	LNCS Inf-L	1861
20	LNCS Neo-L	1862
21	LNCS NeoPt-L	1901
22	LNCS Inf	2328

**MEDICAL DEVICE AUTHORITY**

NO	NAME OF DEVICE	IDENTIFIER
23	LNCS Inf-3	2319
24	LNCS Neo	2329
25	LNCS Neo-3	2320
26	LNCS NeoPt	2330
27	LNCS NeoPt-3	2321
28	LNCS NeoPt-500	2331
29	LNCS Trauma	2411
30	LNCS Newborn Neonatal	2412
31	LNCS Newborn Infant / Pediatrics	2413
32	M-LNCS Amtx	2508
33	M-LNCS Amtx-3	2509
34	M-LNCS Pmtx	2510
35	M-LNCS Pmtx-3	2511
36	M-LNCS E1	2919
37	M-LNCS TFA-1	3856
38	M-LNCS Red TFA-1	3855
39	M-LNCS Inf-L	3670
40	M-LNCS Neo-L	3668
41	M-LNCS NeoPt-L	3669
42	M-LNCS Inf	2512
43	M-LNCS Inf-3	2513
44	M-LNCS Neo	2514
45	M-LNCS Neo-3	2515
46	M-LNCS NeoPt	2516
47	M-LNCS NeoPt-3	2517
48	M-LNCS NeoPt-500	2518



MEDICAL DEVICE AUTHORITY

NO	NAME OF DEVICE	IDENTIFIER
49	M-LNCS Trauma	2521
50	M-LNCS Newborn Neonatal	2519
51	M-LNCS Newborn Infant/Pediatric	2520
52	M-LNCS Blue	2522
53	LNOP Adt	1001
54	LNOP Pdt	1025
55	LNOP Inf-L	1800
56	LNOP Neo-L	1798
57	LNOP NeoPt-L	1651
58	LNOP Trauma	2358
59	LNOP Newborn Neonatal	2203
60	LNOP Newborn Infant/Pediatric	2204
61	LNOP Blue	1970
62	RD SET Adt	4000
63	RD SET Pdt	4001
64	RD SET Inf	4002
65	RD SET Neo	4003
66	RD SET NeoPt	4004
67	RD SET NeoPt-500	4005
68	RD SET Trauma	4011
69	RD SET Newborn Neonatal	4013
70	RD SET Newborn I/P	4012
71	RD Rainbow SET-2 Adt	4026
72	RD Rainbow SET-2 Pdt	4027
73	RD Rainbow SET-2 Inf	4028
74	RD Rainbow SET-2 Neo	4029



MEDICAL DEVICE AUTHORITY

NO	NAME OF DEVICE	IDENTIFIER
75	RD Rainbow SET-3 Adt	4030
76	RD Rainbow SET-3 Pdt	4031
77	RD Rainbow SET-3 Inf	4032
78	RD Rainbow SET-3 Neo	4033
79	RD Rainbow Lite SET-1 Adt	4042
80	RD Rainbow Lite SET-1 Paed	4043
81	RD Rainbow Lite SET-1 Inf	4044
82	RD Rainbow Lite SET-1 Neo	4045
83	Ras-45, Acoustic Respiration	4171
84	O3 regional Oximetry, Adult	3756
85	O3 regional Oximetry, Paed	4235
86	RD SedLine Sensor	4248
87	rainbow ReSposable R2-25 Sensor System	3457
88	rainbow ReSposable R2-20 Sensor System	3458
89	rainbow ReSposable R2-25r Sensors	3395
90	rainbow ReSposable R2-20r Sensors	3411
91	rainbow ReSposable™R2-25a Sensors	2753
92	rainbow ReSposable™ R2-20a Sensors	2755
93	rainbow DCI SC 200	3418
94	rainbow DCIP SC 200	3419
95	rainbow DCI SC 400	3420
96	rainbow DCIP SC 400	3421
97	rainbow DCI SC 1000	3647
98	rainbow DCIP SC 1000	3648
99	rainbow DCI-mini SC 200	3797
100	rainbow DCI-mini SC 400	3798

NO	NAME OF DEVICE	IDENTIFIER
101	rainbow DCI-mini SC 1000	3799
102	rainbow 4D DC Sensor, Small	9400
103	rainbow 4D DC Sensor, Medium	9401
104	rainbow 4D DC Sensor, Large	9402
105	rainbow DCI	2696
106	rainbow DCIP	2697
107	rainbow DCI-6	3657
108	rainbow DCIP-6	3658
109	rainbow DCI-dc3	2201
110	rainbow DCIP-dc3	2069
111	LNCS DCI	1863
112	LNCS DCIP	1864
113	LNCS DBI	2853
114	LNCS TC-I	1895
115	LNCS Y-I	2258
116	LNCS TF-I	1896
117	M-LNCS DCI	2501
118	M-LNCS DCIP	2502
119	M-LNCS DBI	2507
120	M-LNCS TC-I	2503
121	M-LNCS Y-I	2505
122	M-LNCS TF-I	2504
123	LNOP DCI	1269
124	LNOP DCIP	1276
125	LNOP TC-I	1794
126	LNOP TF-I	1793



MEDICAL DEVICE AUTHORITY

NO	NAME OF DEVICE	IDENTIFIER
127	LNOP DC-195	1560
128	LNOP Y-I	1544
129	DCSC	1396
130	DB-I-dc3	2651
131	Red DCI-dc3	2053
132	Red DCIP-dc3	2256
133	Red DBI-dc3	2643
134	LNCS DBI SpO2	2653
135	RD SET DCI	4050
136	RD SET DCI-P	4051
137	RD SET YI	4054
138	Rainbow Super DCI-mini Lite SC 200	4309
139	Rainbow Super DCI-mini Lite SC 400	4310
140	Rainbow Super DCI-mini Lite SC 1000	4311
141	RD SET Tip Clip	4053
142	O3 Infant and Neonatal Sensor	4384
143	RD SET TFA-1 Adult / Pediatric SpO2 disposable tranflectance forehead sensor, 3 ft	4016
144	RD SET Blue Neonatal / Infant / Pediatric SpO2 Adhesive Sensor	4014
145	RD SET E1 Adult SpO2, Disposable Ear Sensor, 3ft	4015
146	RD SET DBI Adult Soft Reusable Sensor, 3ft	4052
147	RD SET Adt CS-2 Adult SpO2 Adhesive Sensor, 2ft	4470
148	RD SET Pft CS-2 Pediatric SpO2 Adhesive Sensor, 2ft	4471
149	RD SET Inf CS-2 Infant SpO2 Adhesive Sensor, 2ft	4472
150	RD SET Neo CS-2 Adult / Neonatal SpO2 Adhesive Sensor, 2ft	4473
151	RD SET NeoPt CS-2 Neonatal SpO2 Adhesive Sensor, 2ft	4474
152	RD SET Adt CS-3 Adult SpO2 Adhesive Sensor, 3ft	4475

NO	NAME OF DEVICE	IDENTIFIER
153	RD SET Pdt CS-3 Pediatric SpO2 Adhesive Sensor, 3ft	4476
154	RD SET Neo CS-3 Adult / Neonatal SpO2 Adhesive Sensor, 3ft	4477
155	RD SET Neo CS-3 Adult / Neonatal SpO2 Adhesive Sensor, 3ft	4478
156	RD SET NeoPt CS-3 Neonatal SpO2 Adhesive Sensor, 3ft	4479
157	RD SET™ TF-1	4055
158	RD SedLine EEG Sensor, Adult	4248
159	RD SedLine EEG Sensor, Pediatric	4329
160	Rainbow DCIP-dc12, Pediatric Reusable, 12 ft. 1/box, (SpO2, SpCO, SpMet)	2070
161	Rainbow DCI-dc12, Adult Reusable Direct Connect Sensor, 12 ft, 1/box (SpO2, SpCO, SpMet)	2202
162	Rainbow DC-3 SC-360, Adult Reusable Sensor, 3 ft, 1/box (SpO2, SpHb), 360 Spot checks	2241
163	Rainbow DC-12 SC-360, Adult Reusable Sensor, 12 ft, 1/box (SpO2, SpHb), 360 Spot checks	2242
164	Rainbow Adult Sample Pack, 1-Rainbow R25 and 1-Rainbow R25-L Sensor SpO2, SpCO, SpMet Sensors	2291
165	Rainbow Ped/Inf Sample Pack, 1 Rainbow R20 and 1 Rainbow R20-L Sensor SpO2, SpCO, SpMet Sensors	2292
166	Rainbow DCI SC-360, Adult Reusable Sensor, 3 ft, 1/box (SpO2, SpHb), 360 Spot checks	2333
167	Rainbow DCIP SC-360, Pediatric Reusable Sensor, 3 ft, 1/box (SpO2, SpHb), 360 Spot checks	2334
168	Rainbow DCP-3 SC-360, Pediatric Reusable Sensor, 3 ft. 1/box, (SpO2, SpHb), 360 Spot checks	2402
169	Rainbow DCP-12 SC-360, Pediatric Reusable Sensor, 12 ft. 1/box, (SpO2, SpHb), 360 Spot checks	2403
170	Rainbow DCI-dc8, Adult Reusable Direct Connect Sensor, 8 ft, 1/box (SpO2, SpCO, SpMet)	2407
171	Rainbow R1 25, Adult Adhesive Sensors (SpO2, SpHb, SpMet), 10/box	2416
172	Rainbow R1 20, Pediatric Adhesive Sensors (SpO2, SpHb, SpMet), 10/box	2417

NO	NAME OF DEVICE	IDENTIFIER
173	Rainbow R1 25 Adult Demo Pack, 2 Rainbow R1 25 SpHb, SpO2, SpMet Sensors	2625
174	Rainbow R1 20 Ped Demo Pack, 2 Rainbow R1 20 SpHb, SpO2, SpMet Sensors	2626
175	Rainbow DCIP-dc8, Pediatric Reusable, 8ft, 1/box (SpO2, SpCO, SpMet)	2640
176	Rainbow DC-3 SC-200, Adult Reusable Sensor, 3 ft, 1/box (SpO2, SpHb), 200 Spot checks	2646
177	Rainbow DCP-3 SC-200, Pediatric Reusable Sensor, 3 ft, 1/box (SpO2, SpHb), 200 Spot checks	2647
178	Rainbow R1 25L Adult Demo Pack, 2 Rainbow R1 25L SpHb, SpO2, SpMet Sensors	2745
179	Rainbow R1 20L Inf Demo Pack, 2 Rainbow R1 20L SpHb, SpO2, SpMet Sensors	2746
180	Rainbow ReSposable R2-25r, Adult Reusable Sensors, SpO2, SpHb & SpMet (5/box)	2754
181	Rainbow ReSposable R2-20r, Pediatric Reusable Sensors, SpO2, SpHb & SpMet (5/box)	2756
182	Rainbow 4D DC SC-500, 500 Spot Check Sensor, SpHb, SpO2, PR, PI	2953
183	Rainbow 4D DC SC-1000, 1000 Spot Check Sensor, SpHb, SpO2, PR, PI	2954
184	RAS-45 Inf/Neo, Acoustic Respiration Sensor, 3ft	4425
185	SpO2.com A, Adult Adhesive Sensors, 24/Box	1774
186	SpO2.com P, Pediatric Adhesive Sensors, 24/Box	1775
187	SpO2.com, Infant Adhesive Sensors, 24/Box	1777
188	SpO2.com, Neonatal Adhesive Sensors, 24/Box	1176