



## DEVICE DETAILS

|                                      |  |
|--------------------------------------|--|
| <b>NAME OF DEVICE</b>                | RAINBOW PULSE OXIMETER   |
| <b>ESTABLISHMENT NAME</b>            | NYPRAX BUSINESS SOLUTIONS  |
| <b>ROLE OF ESTABLISHMENT</b>         | AUTHORIZED REPRESENTATIVE  |
| <b>REGISTRATION NO</b>               | GC430321043618   |
| <b>BRAND NAME</b>                    | MASIMO   |
| <b>MEDICAL DEVICE CATEGORY</b>       | MD 1302 - Monitoring devices of vital physiological parameters   |
| <b>DEVICE GROUPING TYPE</b>          | FAMILY   |
| <b>DEVICE DESCRIPTION</b>            | THE RADICAL-7 PULSE CO-OXIMETER IS A NONINVASIVE MONITOR THAT MEASURES ARTERIAL OXYGEN SATURATION (SPO <sub>2</sub> ), PULSE RATE (PR), AND PERFUSION INDEX (PI), ALONG WITH OPTIONAL MEASUREMENTS OF HEMOGLOBIN (SPHB)*, CARBOXYHEMOGLOBIN (SPCO)*, TOTAL OXYGEN CONTENT (SPOC), METHEMOGLOBIN (SPMET)*, PLETH VARIABILITY INDEX (PVI), OXYGEN RESERVE INDEX (ORI)*, ACOUSTIC RESPIRATION RATE (RRA)*, AND PLETH RESPIRATION RATE (RRP)*.   |
| <b>DEVICE INTENDED PURPOSE</b>       | THE RADICAL-7 PULSE CO-OXIMETER CAN BE USED AS EITHER A HANDHELD OR A STANDALONE MONITOR. THE RADICAL-7 PULSE CO-OXIMETER FEATURES A TOUCHSCREEN THAT CONTINUOUSLY DISPLAYS NUMERIC VALUES FOR ARTERIAL OXYGEN SATURATION (SPO <sub>2</sub> ), PULSE RATE (PR), AND PERFUSION INDEX (PI), ALONG WITH OPTIONAL MEASUREMENTS OF HEMOGLOBIN (SPHB)*, CARBOXYHEMOGLOBIN (SPCO)*, TOTAL OXYGEN CONTENT (SPOC), METHEMOGLOBIN (SPMET)*, PLETH VARIABILITY INDEX (PVI), OXYGEN RESERVE INDEX (ORI)*, ACOUSTIC RESPIRATION RATE (RRA)*, AND PLETH RESPIRATION RATE (RRP)*. |
| <b>VALIDITY DATE OF REGISTRATION</b> | 02/08/2023 - 01/08/2028  |

## LIST OF DEVICE

| NO | NAME OF DEVICE                   | IDENTIFIER |
|----|----------------------------------|------------|
| 1  | Rad-97                           | 9738       |
| 2  | Rad-97 NiBP                      | 9797       |
| 3  | Rad-97 with Nomoline Capnography | 9799       |
| 4  | Radical-7                        | 9500       |
| 5  | Rad-67                           | 9794       |

| NO | NAME OF DEVICE                                       | IDENTIFIER |
|----|--|------------|
| 6  | Pronto Spot Check Pulse CO-Oximeter                  | 9167       |
| 7  | Radius-7   | 9664       |
| 8  | Rad-57 Configurable Pulse CO-Oximeter                | 9216       |
| 9  | Masimo RainbowSET IntelliVue Module                  | 3924       |
| 10 | Root   | 9515       |
| 11 | Root NIBPT   | 9695       |
| 12 | rainbow RC-12, rainbow Patient Cable, 12 ft          | 2404       |
| 13 | rainbow RC-1, rainbow Patient Cable, 1 ft            | 2405       |
| 14 | rainbow RC-4, rainbow Patient Cable, 4 ft            | 2406       |
| 15 | M-LNC-1, M-LNCS Series Patient Cable, 1 ft           | 2523       |
| 16 | M-LNC-4, M-LNCS Series Patient Cable, 4 ft           | 2524       |
| 17 | M-LNC-10, M-LNCS Series Patient Cable, 10 ft         | 2525       |
| 18 | M-LNC-14, M-LNCS Series Patient Cable, 14 ft         | 2526       |
| 19 | M-LNC-10-GE, M-LNCS to GE Patient Cable, 10 ft       | 2533       |
| 20 | M-LNC-04-DB9, M-LNCS to DB9 Patient Cable, 4 ft      | 2534       |
| 21 | M-LNC-10-DB9, M-LNCS to DB9 Patient Cable, 10 ft     | 2535       |
| 22 | M-LNC-14-DB9, M-LNCS to DB9 Patient Cable, 14 ft     | 2536       |
| 23 | M-LNC-4-GE, M-LNCS to GE Patient Cable, 4 ft         | 2655       |
| 24 | M-LNC-SL-10, M-LNCS to Spacelab Patient Cable, 10 ft | 2714       |
| 25 | M-LNC-MP10, M-LNCS to IVM / MMS, 10 ft               | 2831       |
| 26 | RC25-12, rainbow Patient Cable, 12 ft                | 3342       |
| 27 | RC25-12RA, rainbow Patient Cable, 12 ft              | 3343       |
| 28 | RC25-4RA, rainbow Patient Cable, 4 ft                | 3375       |
| 29 | M-LNCS Patient Cable, Red M-LNCv-4                   | 3513       |
| 30 | M-LNCS Patient Cable, Red M-LNCv-10                  | 3514       |
| 31 | RC25-4, rainbow Patient Cable, 4 ft                  | 3628       |

| NO | NAME OF DEVICE  | IDENTIFIER |
|----|---|------------|
| 32 | M-LNC MP4, M-LNCS to IVM / MMS, 4 ft  | 3754       |
| 33 | RC25-1, rainbow Patient Cable, 1ft  | 3933       |
| 34 | RC25-1RA, Patient Cable, 1ft  | 3934       |
| 35 | M-LNC-10-NK, M-LNCS to NK Patient Cable, 10 ft                                      | 3985       |
| 36 | rainbow M20-01, rainbow Patient Cable, 1 ft   | 4236       |
| 37 | rainbow M20-04, rainbow Patient Cable, 4 ft   | 4237       |
| 38 | rainbow M20-12, raionbow Patient Cable, 12 ft                                       | 4238       |
| 39 | rainbow RC-1 EMS, Patient Cable, 1/box  | 4480       |
| 40 | rainbow RC-4 EMS, Patient Cable, 1/box  | 4481       |
| 41 | rainbow RC25-1 EMS, Patient Cable, 1/box  | 4482       |
| 42 | rainbow RC25-4 EMS, Patient Cable, 1/box  | 4483       |
| 43 | rainbow RC25-1RA EMS, Patient Cable, 1/box  | 4484       |
| 44 | rainbow RC25-4RA EMS, Patient Cable, 1/box  | 4485       |
| 45 | spo2.com NRC-180 Patient Cable  | 1810       |
| 46 | spo2.com NRC-395 Patient Cable  | 1811       |
| 47 | spo2.com NRC-P12, Patient Cable   | 1853       |
| 48 | spo2.com NRC-GE Patient Cable   | 1854       |
| 49 | spo2.com NRC-SL , Spacelabs Replacement Cable                                       | 1900       |
| 50 | spo2.com NRC-P8, Patient Cable, 3M  | 1949       |
| 51 | spo2.com NRC-SL2 Spacelabs Replacement Cable  | 2335       |
| 52 | LNCS Red Patient Cable, Red LNCTM-04, LNCS 20-pin SpO2 Patient Cable, 4 ft., 1/Box  | 2055       |
| 53 | LNCS Red Patient Cable, Red LNCTM-10, LNCS 20-pin SpO2 Patient Cable, 10 ft., 1/Box | 2056       |
| 54 | LNCS Red Patient Cable, Red LNCTM-14, LNCS 20-pin SpO2 Patient Cable, 14 ft., 1/Box | 2057       |
| 55 | LNCTM PATIENT CABLE, LNC-4, 4 FT., 1/BOX  | 2017       |

| NO | NAME OF DEVICE  | IDENTIFIER |
|----|---|------------|
| 56 | LNC PATIENT CABLE, LNC-10, 10 FT., 1/BOX  | 1814       |
| 57 | RD rainbow SET Patient Cable, MD20-1.5, RD rainbow 20-pin Patient Cable, 1.5 ft., 1/Box                 | 4071       |
| 58 | RD RAINBOW SET PATIENT CABLE, MD20-05, RD RAINBOW 20-PIN PATIENT CABLE, 5 FT., 1/BOX                    | 4072       |
| 59 | RD RAINBOW SET PATIENT CABLE, MD20-08, RD RAINBOW 20-PIN PATIENT CABLE, 8 FT., 1/BOX                    | 4109       |
| 60 | RD RAINBOW SET PATIENT CABLE, MD20-12, RD RAINBOW 20-PIN PATIENT CABLE, 12 FT., 1/BOX                   | 4073       |
| 61 | RD rainbow SET Patient Cable, 25R-05, RD SET Series, 25-pin Patient Cable, 5 ft., 1/Box 1               | 4076       |
| 62 | RD rainbow SET Patient Cable, 25RA-05, RD SET Series, 25-pin Right Angle Patient Cable, 5 ft., 1/Box 1  | 4077       |
| 63 | RD rainbow SET Patient Cable, 25R-08, RD SET Series, 25-pin Patient Cable, 8 ft., 1/Box 1               | 4106       |
| 64 | RD rainbow SET Patient Cable, 25RA-08, RD SET Series, 25-pin, Right Angle Patient Cable, 8 ft., 1/Box   | 4107       |
| 65 | RD RAINBOW SET PATIENT CABLE, 25R-12, RD SET SERIES, 25-PIN PATIENT CABLE, 12 FT., 1/BOX                | 4078       |
| 66 | RD rainbow SET Patient Cable, 25RA-12, RD SET Series, 25-pin Right Angle Patient Cable, 12 ft., 1/Box   | 4079       |
| 67 | RD SET PATIENT CABLE, MD14-05, 14-PIN RD SET PATIENT CABLE, 5 FT., 1/BOX                                | 4080       |
| 68 | RD SETTM Patient Cable, MD14-08, 14-pin RD SETTM Patient Cable, 8 ft., 1/box                            | 4108       |
| 69 | RD SET PATIENT CABLE, MD14-12, 14-PIN RD SET PATIENT CABLE, 12 FT., 1/BOX                               | 4081       |
| 70 | RD ADAPTER CABLE, RD TO M-LNC ADAPTER CABLE, RD SET SERIES TO M-LNC OR RC PATIENT CABLE, 1.5 FT., 1/BOX | 4090       |
| 71 | RD ADAPTER CABLE, LNCS TO RD ADAPTER CABLE, LNCS SERIES TO RD PATIENT CABLE, 1 FT., 1/BOX               | 4092       |
| 72 | RD SET PATIENT CABLE, MD20-1.5, 20-PIN PATIENT CABLE, 1.5 FT., 1/BOX                                    | 4102       |
| 73 | RD SET PATIENT CABLE, MD20-05, 20-PIN PATIENT CABLE, 5 FT., 1/BOX                                       | 4103       |

| NO | NAME OF DEVICE   | IDENTIFIER |
|----|--|------------|
| 74 | RD SET PATIENT CABLE, MD20-12, 20-PIN PATIENT CABLE, 12 FT., 1/BOX   | 4104       |
| 75 | RD ADAPTER CABLE, RD TO LNC ADAPTER CABLE, RD SET SERIES TO LNC PATIENT CABLE, 1.5 FT., 1/BOX  | 4105       |
| 76 | RD RAINBOW SET PATIENT CABLE, M20-12, RD RAINBOW M20 CONNECTOR PATIENT CABLE, 12 FT., 1/BOX  | 4257       |
| 77 | RD rainbow SET Patient Cable, M20-05, RD rainbow M20 Connector Patient Cable, 5 ft., 1/Box   | 4256       |
| 78 | RD RAINBOW SET PATIENT CABLE, M20-1.5, RD RAINBOW M20 CONNECTOR PATIENT CABLE, 1.5 FT., 1/BOX  | 4255       |
| 79 | RD SEDLINE PATIENT CABLE, 3 FT., 1/BOX   | 4298       |
| 80 | LNC PATIENT CABLE, LNC-10-GE, LNCS TO GE PATIENT CABLE, 10 FT., 1/BOX  | 2016       |
| 81 | LNCTM Patient Cable, LNC-4-GE, LNCS to GE Patient Cable, 4 ft., 1/Box  | 2430       |
| 82 | LNCS DUAL KEY PATIENT CABLE, LNC MP10, LNCS TO INTELLIVUE MASIMO SET OR INTELLIVUE PHILIPS FAST-SPO2, 10 FT., 1/BOX                              | 2281       |
| 83 | LNC PATIENT CABLE, LNC-04-DB9, LNCS TO DB9 CONNECTOR PATIENT CABLE, 4 FT., 1/BOX   | 2285       |
| 84 | RD SETTM Patient Cable, MP-05, RD SETTM to IntelliVue Masimo SET or IntelliVue Philips FAST-SpO2 Dual Key 1 \$190.00 Patient Cable, 5 ft., 1/Box | 4082       |
| 85 | RD SET PATIENT CABLE, MP-12, RD SET TO INTELLIVUE MASIMO SET OR INTELLIVUE PHILIPS FAST-SPO2 DUAL KEY PATIENT CABLE, 12 FT., 1/BOX               | 4083       |
| 86 | RD SETTM Patient Cable, GE-05, RD SETTM to GE Patient Cable, 5 ft., 1/Box  | 4084       |
| 87 | RD SET PATIENT CABLE, GE-12, RD SET TO GE PATIENT CABLE, 12 FT., 1/BOX   | 4085       |
| 88 | RD SET PATIENT CABLE, NK-12, RD SET TO NIHON KOHDEN PATIENT CABLE, 12 FT., 1/BOX   | 4192       |
| 89 | RD SETTM Patient Cable, NK-05, RD SETTM to Nihon Kohden Patient Cable, 5 ft., 1/Box  | 4191       |
| 90 | rainbow RC-EXT-8, Extension Cable, 8 ft., 1/Box  | 3659       |
| 91 | RD rainbow SET RAM Dual Cable MD20-12  | 4279       |
| 92 | RD rainbow SET RAM Dual Cable M20-12   | 4512       |
| 93 | RD rainbow SET RAM Dual Cable R25-12   | 4278       |

| NO  | NAME OF DEVICE   | IDENTIFIER |
|-----|--|------------|
| 94  | RAM Dual Cable, LNC-10, 1/Box  | 3661       |
| 95  | RAM Dual Cable LNC M20-10, 1/Box   | 4099       |
| 96  | RAM Dual Cable, Red 25 LNC-10, 1/Box   | 3906       |
| 97  | RAM Dual Cable, RC-10, 1/Box   | 3660       |
| 98  | RAM Dual Cable M20-10, 1/Box   | 4100       |
| 99  | RAM Dual Cable, RC25-10, 1/Box   | 3503       |
| 100 | RD SET Patient Cable, RD SET SL-12, RD SET to SpaceLabs Patient Cable, 12 ft., 1/Box               | 4087       |
| 101 | RD Extension Cable, RD EXT-4, 4 ft., 1/Box   | 4095       |
| 102 | RD Adapter Cable, RD to PC Adapter Cable, RD SET Series to LNOP PC Patient Cable, 1.5 ft., 1/Box   | 4088       |
| 103 | RD Adapter Cable, RD to LNC Adapter Cable, RD SET Series to LNC Patient Cable, 3 ft., 1/Box        | 4089       |
| 104 | RD Adapter Cable, LNOP to RD Adapter Cable, LNOP Series to RD Patient Cable, 1.5 ft., 1/Box        | 4091       |
| 105 | LNCS Red Patient Cable, Red LNC M20-01, LNCS M20 Connector Spot Check Patient Cable, 1 ft., 1/Box  | 4251       |
| 106 | LNCS Red Patient Cable, Red LNC M20-04, LNCS M20 Connector Patient Cable, 4 ft., 1/Box             | 4252       |
| 107 | LNCS Red Patient Cable, Red LNC M20-10, LNCS M20 Connector Patient Cable, 10 ft., 1/Box            | 4253       |
| 108 | LNCS Red Patient Cable, Red LNC M20-14, LNCS M20 Connector Patient Cable, 14 ft., 1/Box            | 4254       |
| 109 | LNCS Red Patient Cable, Red LNCTM-01, LNCS 20-pin SpO2 Spot Check Patient Cable, 1 ft., 1/Box      | 2365       |
| 110 | LNC Patient Cable, LNC-1, 1 ft., 1/Box   | 2364       |
| 111 | LNCS Red Patient Cable, Red 25 LNC-1, LNCS Series 25-pin Patient Cable, 1 ft., 1/Box               | 3935       |
| 112 | LNCS Red Patient Cable, Red 25 LNC-4, 25-pin, 4 ft., 1/Box   | 3630       |
| 113 | LNCS Red Patient Cable, Red 25 LNC-1RA, LNCS Series 25-pin Right Angle Patient Cable, 1 ft., 1/Box | 3936       |

| NO  | NAME OF DEVICE   | IDENTIFIER |
|-----|--|------------|
| 114 | LNCS Red Patient Cable, Red 25 LNC-4RA, 25-pin, 4 ft., 1/Box                                 | 3376       |
| 115 | LNCS Red Patient Cable, Red 25 LNC-10, 25-pin, 10 ft., 1/Box                                 | 3345       |
| 116 | LNC Patient Cable, LNC MP4, M-LNCS Dual Key Patient Cable, 4 ft., 1/Box                      | 3755       |
| 117 | LNC Patient Cable, LNC-10-DB9, LNCS to DB9 Connector Patient Cable, 10 ft., 1/Box            | 2286       |
| 118 | LNC Patient Cable, LNC-10-NK, LNCS to Nihon Kohden Patient Cable, 10 ft., 1/Box              | 3984       |
| 119 | LNCS Adapter Cable, LNCS Series to LNOP PC Adapter Cable, 18 inch, 1/Box                     | 1816       |
| 120 | LNCS Adapter Cable, CMS, LNCS Series to Philips 12-pin Instrument Adapter Cable, 3 m, 1/Box  | 2263       |
| 121 | LNCS Adapter Cable, MAC-GE, LNCS Series to GE Adapter Cable, 3 m, 1/Box                      | 2264       |
| 122 | LNCS Adapter Cable, MAC-SL, LNCS Series to Spacelabs Adapter Cable, 3 m, 1/Box               | 2266       |
| 123 | LNCS Adapter Cable, MAC-SL2, LNCS Series to Spacelabs Adapter Cable, 3 m, 1/Box              | 2336       |
| 124 | LNCS Adapter Cable, MAC-180, LNCS Series to N-180 Adapter Cable, 10 ft., 1/Box               | 2268       |
| 125 | LNCS Adapter Cable, MAC-395, LNCS Series to N-395 Adapter Cable, 10 ft., 1/Box               | 2269       |
| 126 | Adapter Cable, 14-pin to 20-pin, Connect PXC2 to Masimo SET 20-pin Devices, SpO2 only, 1/Box | 2478       |
| 127 | Mountable Extension Cable, PXC2-16, 16 ft., 1/Box  | 2371       |
| 128 | Mountable Extension Cable, PXC2-30, 30 ft., 1/Box  | 2373       |
| 129 | Radical Docking Station, RDS-1   | 9021       |
| 130 | Radical Docking Station, RDS-3   | 9023       |
| 131 | RD rainbow SET R25-1.5   | 4074       |
| 132 | RD rainbow SET RA25-1.5  | 4075       |
| 133 | RD rainbow SET MD20-1.5, EMS   | 4791       |
| 134 | RD rainbow SET MD20-04, EMS  | 4792       |
| 135 | RD rainbow SET MD20-12, EMS  | 4793       |
| 136 | RD rainbow SET R25-1.5, EMS  | 4794       |

| NO  | NAME OF DEVICE               | IDENTIFIER |
|-----|------------------------------|------------|
| 137 | RD rainbow SET R25-04, EMS   | 4795       |
| 138 | RD rainbow SET R25-12, EMS   | 4796       |
| 139 | RD rainbow SET RA25-1.5, EMS | 4797       |
| 140 | RD rainbow SET RA25-04, EMS  | 4798       |
| 141 | RD rainbow SET RA25-12, EMS  | 4799       |
| 142 | RD SET MD14-1.5              | 4675       |
| 143 | RD SET Rad-G-1.5             | 4772       |
| 144 | RD SET Rad-G-5               | 4773       |
| 145 | RD SET Rad-G-12              | 4774       |



**MEDICAL DEVICE AUTHORITY**