



DEVICE DETAILS

NAME OF DEVICE	PICOWAY LASER SYSTEM
ESTABLISHMENT NAME	BEAUMEDIC AESTHETIC (M) SDN.BHD.
ROLE OF ESTABLISHMENT	AUTHORIZED REPRESENTATIVE
REGISTRATION NO	GC5327823-144772
BRAND NAME	CANDELA
MEDICAL DEVICE CATEGORY	MD 1402 - Devices utilising non-ionizing radiation
DEVICE GROUPING TYPE	FAMILY
DEVICE DESCRIPTION	The PicoWay Laser System is a solid-state laser capable of delivering energy at wavelengths of 1064 nm, 532 nm, 730 nm (new) or 785 nm at extremely short duration in the range of 240-500 ps. The laser system contains one 755 nm (Alexandrite) laser head which is used to 'pump' (create) the 1064 nm picosecond wavelength. The 1064 nm wavelength can be frequency-doubled to 532 nm as desired. The outputs of the two lasers are designed to be co-linear on the laser rail so that their beam paths are identical as they exit the laser system. This allows the use of a single delivery system which can output either the 532 nm or 1064 nm wavelengths. The current 785 nm and new 730 nm wavelength contain a Ti:Sapphire laser rod that is pumped with the 532 nm energy. All these energies are delivered through an articulated arm and corresponding handpiece.
DEVICE INTENDED PURPOSE	The PicoWay laser system is indicated for the following at the specified wavelength: ● 532 nm: Removal of tattoos for Fitzpatrick Skin Types I-III to treat the following tattoo colors: red, yellow and orange. ● 730 nm: Removal of tattoos for Fitzpatrick Skin Types I-IV to treat the following tattoo colors: green and blue. ● 785 nm: Removal of tattoos for Fitzpatrick Skin Types II-IV to treat the following tattoo colors: green and blue. ● 1064 nm: Removal of tattoos for all Fitzpatrick Skin Types to treat the following tattoo colors: black, brown, green, blue and purple. The PicoWay laser system is also indicated for benign pigmented lesions removal for Fitzpatrick Skin Types I-IV. The Resolve handpiece (1064 nm) is also indicated for the treatment of acne scars in Fitzpatrick Skin Types II-V and for treatment of Melasma for Fitzpatrick Skin Types I-IV. The Resolve handpieces (532 nm HE, 532 nm, and 1064 nm) are also indicated for the treatment of wrinkles in Fitzpatrick Skin Types I-IV. The Resolve Fusion handpiece (532 nm) is indicated for benign pigmented lesions removal for Fitzpatrick Skin Types II-V. The PicoWay laser system is indicated for the following at the specified wavelengths: 532 nm: ● Treatment of Melasma for Fitzpatrick Skin Types I-IV. ● Treatment of café au lait macules (CALMs) for Fitzpatrick Skin Types I-IV. ● Treatment of Lentigines for Fitzpatrick Skin Types I-IV. 730 nm: ● Treatment of Lentigines for Fitzpatrick Skin Types I-IV. 1064 nm: ● Treatment of Melasma for Fitzpatrick Skin Types I-IV. ● Treatment of Nevus of Ota for Fitzpatrick Skin Types III-IV.
VALIDITY DATE OF REGISTRATION	16/08/2023 - 15/08/2028

LIST OF DEVICE

NO	NAME OF DEVICE	IDENTIFIER
1	PicoWay Laser System	9914-00-9060
2	PicoWay Laser System	9914-JB-9060
3	Articulated Arm Cable	6032-00-0410
4	Zoom Handpiece	7122-00-4052
5	Resolve Fractional Handpiece - 1064 nm	7123-00-0059
6	Resolve Fractional Handpiece - 532 nm	7123-00-0592
7	Resolve Fractional Handpiece - 532 nm HE	7123-00-0593
8	Resolve Fusion Handpiece - 532nm	7123-00-0536
9	Resolve Fusion Handpiece - 1064nm	7123-00-0594
10	Handpiece - 730nm	7123-00-0497
11	Handpiece - 785nm	7123-00-0191
12	Distance Gauge Kit (Zoom)	7123-00-0467
13	Distance Gauge 2 mm (785 nm)	7123-00-0192
14	Distance Gauge 3 mm (785 nm)	7123-00-0193
15	Distance Gauge 4 mm (785 nm)	7123-00-0194
16	Distance Gauge 2mm (730 nm)	7123-00-0498
17	Distance Gauge 3mm (730 nm)	7123-00-0499
18	Distance Gauge 4mm (730 nm)	7123-00-0500
19	Resolve Distance Gauge Kit	7123-00-0596
20	Footswitch	5103-00-0030
21	Power Cable	7122-00-3330
22	User Goggles	8095-00-0488
23	Patient Goggles	8095-00-0470
24	Window Kit, Zoom, Resolve and Resolve Fusion	7123-00-0555
25	Window Kit, 785 and 730 nm	7123-00-0556

NO	NAME OF DEVICE	IDENTIFIER
26	PicoWay Laser System	9914-00-9060
27	PicoWay Laser System	9914-C1-9060
28	PicoWay Laser System	9914-C2-9060
29	PicoWay Laser System	9914-CH-9060
30	Articulated Arm Cable	6032-00-0410
31	Zoom Handpiece	7122-00-4052
32	Resolve Fractional Handpiece - 1064 nm	7123-00-0059
33	Resolve Fractional Handpiece - 532 nm	7123-00-0592
34	Resolve Fractional Handpiece - 532 nm HE	7123-00-0593
35	Resolve Fusion Handpiece - 532nm	7123-00-0536
36	Resolve Fusion Handpiece - 1064nm	7123-00-0594
37	Handpiece - 730nm	7123-00-0497
38	Handpiece - 785nm	7123-00-0191
39	Distance Gauge Kit (Zoom)	7123-00-0467
40	Distance Gauge 2 mm (785 nm)	7123-00-0192
41	Distance Gauge 3 mm (785 nm)	7123-00-0193
42	Distance Gauge 4 mm (785 nm)	7123-00-0194
43	Distance Gauge 2mm (730 nm)	7123-00-0498
44	Distance Gauge 3mm (730 nm)	7123-00-0499
45	Distance Gauge 4mm (730 nm)	7123-00-0500
46	Resolve Distance Gauge Kit	7123-00-0596
47	Footswitch	5103-00-0030
48	Power Cable	7122-00-3330
49	User Goggles	8095-00-0488
50	Patient Goggles	8095-00-0470
51	Window Kit, Zoom, Resolve and Resolve Fusion	7123-00-0555

NO	NAME OF DEVICE	IDENTIFIER
52	Window Kit, 785 and 730 nm	7123-00-0556
53	PicoWay Laser System	9914-00-9060
54	PicoWay Laser System	9914-JB-9060
55	PicoWay Laser System	9914-C1-9060
56	PicoWay Laser System	9914-C2-9060
57	PicoWay Laser System	9914-CH-9060
58	Articulated Arm Cable	6032-00-0410
59	Zoom Handpiece	7122-00-4052
60	Resolve Fractional Handpiece - 1064 nm	7123-00-0059
61	Resolve Fractional Handpiece - 532 nm	7123-00-0592
62	Resolve Fractional Handpiece - 532 nm HE	7123-00-0593
63	Resolve Fusion Handpiece - 532nm	7123-00-0536
64	Resolve Fusion Handpiece - 1064nm	7123-00-0594
65	Handpiece - 730nm	7123-00-0497
66	Handpiece - 785nm	7123-00-0191
67	Distance Gauge Kit (Zoom)	7123-00-0467
68	Distance Gauge 2 mm (785 nm)	7123-00-0192
69	Distance Gauge 3 mm (785 nm)	7123-00-0193
70	Distance Gauge 4 mm (785 nm)	7123-00-0194
71	Distance Gauge 2mm (730 nm)	7123-00-0498
72	Distance Gauge 3mm (730 nm)	7123-00-0499
73	Distance Gauge 4mm (730 nm)	7123-00-0500
74	Resolve Distance Gauge Kit	7123-00-0596
75	Footswitch	5103-00-0030
76	Power Cable	7122-00-3330
77	User Goggles	8095-00-0488

NO	NAME OF DEVICE	IDENTIFIER
78	Patient Goggles	8095-00-0470
79	Window Kit, Zoom, Resolve and Resolve Fusion	7123-00-0555
80	Window Kit, 785 and 730 nm	7123-00-0556



MEDICAL DEVICE AUTHORITY