



DEVICE DETAILS

NAME OF DEVICE	SKYPULSE
ESTABLISHMENT NAME	VENUSYS MEDICAL SDN BHD
ROLE OF ESTABLISHMENT	AUTHORIZED REPRESENTATIVE
REGISTRATION NO	GC6239524-179855
BRAND NAME	FOTONA
MEDICAL DEVICE CATEGORY	MD 1402 - Devices utilising non-ionizing radiation
DEVICE GROUPING TYPE	FAMILY
DEVICE DESCRIPTION	The SkyPulse laser system family consists of two different versions: • SkyPulse M321-A abbreviated as SkyPulse Versa / Endo Pro which has XS-A Er:YAG laser module and offers water spray for cooling the treated area or Endo Plus which can have XS- A or XSC Er:YAG laser module and also offers water spray for cooling the treated area. • SkyPulse M321-B abbreviated as SkyPulse Endo which has XSB Er:YAG laser module and does not offer water spray for cooling the treated area.
DEVICE INTENDED PURPOSE	The device and its accessories are intended to be used in dentistry, aesthetics, dermatology, ENT, surgery and pain management.
VALIDITY DATE OF REGISTRATION	17/08/2024 - 16/08/2029

LIST OF DEVICE



NO	NAME OF DEVICE	IDENTIFIER
1	Skypulse (M321-A)	101033
2	Handpiece HC02-N	90669
3	Handpiece HC14-N	90668
4	Handpiece HC14-NS	95734
5	Handpiece HC14-NE	103740
6	Handpiece R17	90039
7	Handpiece R21-C3	90011
8	Handpiece R24-S	105629
9	Handpiece Genova	102631
10	Handpiece MarcCo S	104563
11	Handpiece MarcCo M	104283

NO	NAME OF DEVICE	IDENTIFIER
12	Handpiece MarcCo L	104560
13	Cylindrical Sapphire 1300/8	71766
14	Cylindrical Sapphire 1300/12	72558
15	Conical Sapphire 600/8	72937
16	Flat Chiseled 500/12	72561
17	Radial, Sweeps 400/14	90333
18	Radial, Sweeps 600/14	90334
19	Conical Sapphire 800/8	72560
20	Conical Sapphire 800/12	72856
21	Flat Sweeps 300/20	83890
22	Flat Sweeps 400/14	84827
23	Flat Varian 500/14	84837
24	Flat Varian 600/9 	84838
25	Flat Varian 600/14	84839
26	Conical Sapphire 600/10	99128
27	Conical Sapphire 600/12	72857
28	Conical Sapphire 600/16	85830
29	Flat Sweeps 300/9	102037
30	Flat Sweeps 400/9	84826
31	Radial Sweeps 400/9	102036
32	Flat Varian 500/9	84836
33	Radial, Sweeps 600/9	102135
34	Thin Chisel 150/12	110325
35	Cylindrical Sapphire 1000/4	112782
36	Cylindrical Sapphire 1000/8	112781
37	Cylindrical Sapphire 1000/12	112779

NO	NAME OF DEVICE	IDENTIFIER
38	Radial Sweeps 400/14	90333
39	Radial Sweeps 600/14	90334
40	Flat Sweeps 300/20	83890
41	Flat Sweeps 400/14	84827
42	Conical Sapphire 600/10	99128
43	Flat Sweeps 300/9	102037
44	Flat Sweeps 400/9	84826
45	Radial Sweeps 400/9	102036
46	Radial, Sweeps 600/9	102135
47	Thin Chisel 150/12	110325
48	Cylindrical Sapphire 1000/4	112782
49	Cylindrical Sapphire 1000/8	112781
50	Laser module LM XS-A 	101468
51	Laser module LM XS-B	101469
52	Laser module LM XS-C	106020
53	Laser module LM XS-AF	110664
54	Laser module LM XS-BF	110665
55	Laser module LM XS-CF	110666
56	Laser module LM XD-10	102821
57	Laser module LM XD-10/19	102824
58	Laser module LM XD-67/10	102825
59	Laser module LM XD-67/80/10F	108970
60	Trolley SkyPulse	103240
61	Trolley SkyPulse 1	104660
62	Trolley EM 3/2	105018
63	Foot switch LW	87593

NO	NAME OF DEVICE	IDENTIFIER
64	Foot switch BLE	111629
65	Skypulse (M321-B)	101398
66	Handpiece HC02-N	90669
67	Handpiece HC14-N	90668
68	Handpiece HC14-NS	95734
69	Handpiece HC14-NE	103740
70	Handpiece R17	90039
71	Handpiece R21-C3	90011
72	Handpiece R24-S	105629
73	Handpiece Genova	102631
74	Handpiece MarcCo S	104563
75	Handpiece MarcCo M	104283
76	Handpiece MarcCo L 	104560
77	Cylindrical Sapphire 1300/8	71766
78	Cylindrical Sapphire 1300/12	72558
79	Conical Sapphire 600/8	72937
80	Flat Chiseled 500/12	72561
81	Radial, Sweeps 400/14	90333
82	Radial, Sweeps 600/14	90334
83	Conical Sapphire 800/8	72560
84	Conical Sapphire 800/12	72856
85	Flat Sweeps 300/20	83890
86	Flat Sweeps 400/14	84827
87	Flat Varian 500/14	84837
88	Flat Varian 600/9	84838
89	Flat Varian 600/14	84839

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90	Conical Sapphire 600/10	99128
91	Conical Sapphire 600/12	72857
92	Conical Sapphire 600/16	85830
93	Flat Sweeps 300/9	102037
94	Flat Sweeps 400/9	84826
95	Radial Sweeps 400/9	102036
96	Flat Varian 500/9	84836
97	Radial, Sweeps 600/9	102135
98	Thin Chisel 150/12	110325
99	Cylindrical Sapphire 1000/4	112782
100	Cylindrical Sapphire 1000/8	112781
101	Cylindrical Sapphire 1000/12	112779
102	Radial Sweeps 400/14 	90333
103	Radial Sweeps 600/14	90334
104	Flat Sweeps 300/20	83890
105	Flat Sweeps 400/14	84827
106	Conical Sapphire 600/10	99128
107	Flat Sweeps 300/9	102037
108	Flat Sweeps 400/9	84826
109	Radial Sweeps 400/9	102036
110	Radial, Sweeps 600/9	102135
111	Thin Chisel 150/12	110325
112	Cylindrical Sapphire 1000/4	112782
113	Cylindrical Sapphire 1000/8	112781
114	Laser module LM XS-A	101468
115	Laser module LM XS-B	101469

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116	Laser module LM XS-C	106020
117	Laser module LM XS-AF	110664
118	Laser module LM XS-BF	110665
119	Laser module LM XS-CF	110666
120	Laser module LM XD-10	102821
121	Laser module LM XD-10/19	102824
122	Laser module LM XD-67/10	102825
123	Laser module LM XD-67/80/10F	108970
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125	Trolley SkyPulse 1	104660
126	Trolley EM 3/2	105018
127	Foot switch LW	87593
128	Foot switch BLE 	111629