



## DEVICE DETAILS

<b>NAME OF DEVICE</b>	SKYPULSE
<b>ESTABLISHMENT NAME</b>	VENUSYS MEDICAL SDN BHD
<b>ROLE OF ESTABLISHMENT</b>	AUTHORIZED REPRESENTATIVE
<b>REGISTRATION NO</b>	GC6239524-179855
<b>BRAND NAME</b>	FOTONA
<b>MEDICAL DEVICE CATEGORY</b>	MD 1402 - Devices utilising non-ionizing radiation
<b>DEVICE GROUPING TYPE</b>	FAMILY
<b>DEVICE DESCRIPTION</b>	The SkyPulse laser system family consists of two different versions: <ul style="list-style-type: none"> <li>• 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.</li> <li>• 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.</li> </ul>
<b>DEVICE INTENDED PURPOSE</b>	The device and its accessories are intended to be used in dentistry, aesthetics, dermatology, ENT, surgery and pain management.
<b>VALIDITY DATE OF REGISTRATION</b>	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

NO	NAME OF DEVICE	IDENTIFIER
11	Handpiece MarcCo M	104283
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

<b>NO</b>	<b>NAME OF DEVICE</b>	<b>IDENTIFIER</b>
37	Cylindrical Sapphire 1000/12	112779
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

<b>NO</b>	<b>NAME OF DEVICE</b>	<b>IDENTIFIER</b>
63	Foot switch LW	87593
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

<b>NO</b>	<b>NAME OF DEVICE</b>	<b>IDENTIFIER</b>
89	Flat Varian 600/14	84839
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

<b>NO</b>	<b>NAME OF DEVICE</b>	<b>IDENTIFIER</b>
115	Laser module LM XS-B	101469
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
124	Trolley SkyPulse	103240
125	Trolley SkyPulse 1	104660
126	Trolley EM 3/2	105018
127	Foot switch LW	87593
128	Foot switch BLE	111629

MEDICAL DEVICE AUTHORITY