



DEVICE DETAILS

NAME OF DEVICE	LIGHTWALKER
ESTABLISHMENT NAME	VENUSYS MEDICAL SDN BHD
ROLE OF ESTABLISHMENT	AUTHORIZED REPRESENTATIVE
REGISTRATION NO	GC6207824-164079
BRAND NAME	FOTONA
MEDICAL DEVICE CATEGORY	MD 1100 - GENERAL ACTIVE MEDICAL DEVICES
DEVICE GROUPING TYPE	FAMILY
DEVICE DESCRIPTION	Fotona LightWalker laser system incorporates treatment lasers that operate in the invisible near (Nd:YAG 1064 nm) and mid-infrared (Er:YAG 2940 nm) ranges of the electromagnetic spectrum, and an aiming beam that operates in the visible range. The system combines one or two (depending on the model) flashlamp-pumped solid-state laser sources in one housing, with optical cavities containing the Nd:YAG and/or Er:YAG crystals. The diode aiming beam, which is a semiconductor diode laser with a wavelength of 650, 635 or 520-532 nm (depending on the model), is combined with both therapeutic laser beams. The combined therapeutic and aiming beams are guided through an articulated arm to an optical hand piece (in the case of the Er:YAG laser), or, in the case of the Nd:YAG laser, through an optical fiber delivery system to an optical handpiece or to bare fiber distal end.
DEVICE INTENDED PURPOSE	The device and its accessories are intended to be used in the fields of dentistry, aesthetics, dermatology, gynaecology and urology, ENT, surgery and pain management.
VALIDITY DATE OF REGISTRATION	25/02/2024 - 24/02/2029

LIST OF DEVICE

NO	NAME OF DEVICE	IDENTIFIER
1	LightWalker DT STAND (M021-5AF/2 STAND)	94210
2	HP R02-C CE ENG	69020
3	HP R14-C CE ENG	69084
4	HP R09-2GU CE ENG	93149
5	HP R21-A CE ENG	80214
6	HP R21-C2 CE ENG	90010
7	HP R21-C3 CE ENG	90011
8	HP R24-C CE ENG	67212

NO	NAME OF DEVICE	IDENTIFIER
9	Laser Safety Eyeware	98078
10	Laser Safety Eyeware	99455
11	Laser Safety Eyeware	101081
12	Protective Cap for Patient	68127
13	Protective Cap for Patient	80846
14	Protective Cap for Patient	80847
15	Protective Cap for Patient	85260
16	Footswitch	87593
17	Footswitch	89199
18	TimeWalker ST-E (M002-6A/2)	103175
19	HP R11 CE ENG	58619
20	HP R11-7 CE ENG	103690
21	HP PS03X CE ENG 	100273
22	HP PS03X-7 CE ENG	103478
23	HP R04-Ti CE ENG	82670
24	HP FS01 CE ENG	88618
25	HP R08-Ti CE ENG	68276
26	HP R02-C CE ENG	69081
27	HP R14-C CE ENG	69084
28	HP HC14-NS CE ENG	95156
29	HP HC14-NE CE ENG	103611
30	G-Runner	96381
31	GA Adapter	88925
32	GC Adapter	88928
33	Speculum Standard	88920
34	Speculum Slim	92220

NO	NAME OF DEVICE	IDENTIFIER
35	Speculum Slim Long	93784
36	Speculum Mclear	92899
37	Speculum Sclear	99621
38	SPECULUM GR 25 R	96266
39	SPECULUM GR 30 R	96267
40	SPECULUM GR 25	100803
41	SPECULUM GR 30	100804
42	Laser Safety Eyeware	98078
43	Laser Safety Eyeware	99455
44	Laser Safety Eyeware	101081
45	Protective Cap for Patient	68127
46	Protective Cap for Patient	80846
47	Protective Cap for Patient 	80847
48	Protective Cap for Patient	85260
49	Footswitch	87593
50	Footswitch	89199
51	TimeWalker AT (M021-5AF/1)	103046
52	HP R11 CE ENG	58619
53	HP R11-7 CE ENG	103690
54	HP PS03X CE ENG	100273
55	HP PS03X-7 CE ENG	103478
56	HP R04-Ti CE ENG	82670
57	HP FS01 CE ENG	88618
58	HP R08-Ti CE ENG	68276
59	HP R02-C CE ENG	69081
60	HP R14-C CE ENG	69084

NO	NAME OF DEVICE	IDENTIFIER
61	HP HC14-NS CE ENG	95156
62	HP HC14-NE CE ENG	103611
63	X-Restart	107315
64	G-Runner	96381
65	GA Adapter	88925
66	GC Adapter	88928
67	Speculum Standard	88920
68	Speculum Slim	92220
69	Speculum Slim Long	93784
70	Speculum Mclear	92899
71	Speculum Sclear	99621
72	SPECULUM GR 25 R	96266
73	SPECULUM GR 30 R 	96267
74	SPECULUM GR 25	100803
75	SPECULUM GR 30	100804
76	GENOVA	95969
77	HP MarcCo CE ENG	NA
78	HP MARCCO S CE ENG	104563
79	HP MARCCO M CE ENG	104283
80	HP MARCCO L CE ENG	104560
81	HP R27-C CE ENG	89672
82	HP R30 CE ENG	63302
83	HP R33-T CE ENG	93457
84	HP R30Y CE ENG	103304
85	MATRIXVIEW TW	109329
86	Laser Safety Eyeware	98078

NO	NAME OF DEVICE	IDENTIFIER
87	Laser Safety Eyeware	99455
88	Laser Safety Eyeware	101081
89	Protective Cap for Patient	68127
90	Protective Cap for Patient	80846
91	Protective Cap for Patient	80847
92	Protective Cap for Patient	85260
93	Footswitch	87593
94	Footswitch	89199
95	LightWalker AT S (M021-5AF/1 S)	94205
96	HP H02-N CE ENG	90693
97	HP H14-N CE ENG	90692
98	HP H14-NS CE ENG	95156
99	HP R15 CE ENG 	87342
100	HP R16 CE ENG	87343
101	HP R17 CE ENG	90039
102	HP PS04 CE ENG	91174
103	HP PS04-LA CE ENG	105884
104	HP SX02 CE ENG	92700
105	HP R21-C2 CE ENG	90010
106	HP R21-C3CE ENG	90011
107	HP R30-A CE ENG	75158
108	HP R24-C CE ENG	67212
109	GENOVA	95969
110	HP MarcCo CE ENG	NA
111	HP MARCCO S CE ENG	104563
112	HP MARCCO M CE ENG	104283

NO	NAME OF DEVICE	IDENTIFIER
113	HP MARCCO L CE ENG	104560
114	Laser Safety Eyeware	98078
115	Laser Safety Eyeware	99455
116	Laser Safety Eyeware	101081
117	Protective Cap for Patient	68127
118	Protective Cap for Patient	80846
119	Protective Cap for Patient	80847
120	Protective Cap for Patient	85260
121	Footswitch	87593
122	Footswitch	89199
123	LightWalker ST-E ADVANCED (M002-6A/2 ADVANCED)	98579
124	HP H02-N CE ENG	90693
125	HP H14-N CE ENG 	90692
126	HP H14-NS CE ENG	95156
127	HP R15 CE ENG	87342
128	HP R16 CE ENG	87343
129	HP R17 CE ENG	90039
130	HP PS04 CE ENG	91174
131	HP PS04-LA CE ENG	105884
132	HP SX02 CE ENG	92700
133	Laser Safety Eyeware	98078
134	Laser Safety Eyeware	99455
135	Laser Safety Eyeware	101081
136	Protective Cap for Patient	68127
137	Protective Cap for Patient	80846
138	Protective Cap for Patient	80847

NO	NAME OF DEVICE	IDENTIFIER
139	Protective Cap for Patient	85260
140	Footswitch	87593
141	Footswitch	89199
142	LightWalker ST-E PRO (M002-6A/2 PRO)	98577
143	HP H02-N CE ENG	90693
144	HP H14-N CE ENG	90692
145	HP H14-NS CE ENG	95156
146	Laser Safety Eyeware	98078
147	Laser Safety Eyeware	99455
148	Laser Safety Eyeware	101081
149	Protective Cap for Patient	68127
150	Protective Cap for Patient	80846
151	Protective Cap for Patient 	80847
152	Protective Cap for Patient	85260
153	Footswitch	87593
154	Footswitch	89199