



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 AT S (M021-5AF/1 S)	114113
2	HP H02-N CE ENG	90693
3	HP H14-N CE ENG	90692
4	HP H14-NS CE ENG	95156
5	HP R15 CE ENG	87342
6	HP R16 CE ENG	87343
7	HP R17 CE ENG	90039

NO	NAME OF DEVICE	IDENTIFIER
8	HP PS04 CE ENG	91174
9	HP PS04-LA CE ENG	105884
10	HP SX02 CE ENG	92700
11	HP R21-C2 CE ENG	90010
12	HP R21-C3CE ENG	90011
13	HP R30-A CE ENG	75158
14	HP R24-C CE ENG	67212
15	GENOVA	95969
16	HP MarcCo CE ENG	NA
17	HP MARCCO S CE ENG	104563
18	HP MARCCO M CE ENG	104283
19	HP MARCCO L CE ENG	104560
20	Laser Safety Eyeware	98078
21	Laser Safety Eyeware	99455
22	Laser Safety Eyeware	101081
23	Protective Cap for Patient	68127
24	Protective Cap for Patient	80846
25	Protective Cap for Patient	80847
26	Protective Cap for Patient	85260
27	Footswitch	87593
28	Footswitch	89199
29	SAFETY GOGGLES ER/ND	107211
30	SAFETY GOOGLES ER/ND INNOVATIVE OPTICS 701W.G11	110732
31	LightWalker ST-E ADVANCED (M002-6A/2 ADVANCED)	114117
32	HP H02-N CE ENG	90693
33	HP H14-N CE ENG	90692



MEDICAL DEVICE AUTHORITY

NO	NAME OF DEVICE	IDENTIFIER
34	HP H14-NS CE ENG	95156
35	HP R15 CE ENG	87342
36	HP R16 CE ENG	87343
37	HP R17 CE ENG	90039
38	HP PS04 CE ENG	91174
39	HP PS04-LA CE ENG	105884
40	HP SX02 CE ENG	92700
41	Laser Safety Eyeware	98078
42	Laser Safety Eyeware	99455
43	Laser Safety Eyeware	101081
44	Protective Cap for Patient	68127
45	Protective Cap for Patient	80846
46	Protective Cap for Patient	80847
47	Protective Cap for Patient	85260
48	Footswitch	87593
49	Footswitch	89199
50	SAFETY GOGGLES ER/ND	107211
51	SAFETY GOOGLES ER/ND INNOVATIVE OPTICS 701W.GI1	110732
52	LightWalker ST-E PRO (M002-6A/2 PRO)	114115
53	HP H02-N CE ENG	90693
54	HP H14-N CE ENG	90692
55	HP H14-NS CE ENG	95156
56	Laser Safety Eyeware	98078
57	Laser Safety Eyeware	99455
58	Laser Safety Eyeware	101081
59	Protective Cap for Patient	68127



MEDICAL DEVICE AUTHORITY

NO	NAME OF DEVICE	IDENTIFIER
60	Protective Cap for Patient	80846
61	Protective Cap for Patient	80847
62	Protective Cap for Patient	85260
63	Footswitch	87593
64	Footswitch	89199
65	SAFETY GOGGLES ER/ND	107211
66	SAFETY GOOGLES ER/ND INNOVATIVE OPTICS 701W.G11	110732
67	TimeWalker ST-E (M002-6A/2)	114111
68	HP R11 CE ENG	58619
69	HP R11-7 CE ENG	103690
70	HP PS03X CE ENG	100273
71	HP PS03X-7 CE ENG	103478
72	HP R04-Ti CE ENG	82670
73	HP FS01 CE ENG	88618
74	HP R08-Ti CE ENG	68276
75	HP R02-C CE ENG	69081
76	HP R14-C CE ENG	69084
77	HP HC14-NS CE ENG	95156
78	HP HC14-NE CE ENG	103611
79	G-Runner	96381
80	GA Adapter	88925
81	GC Adapter	88928
82	Speculum Standard	88920
83	Speculum Slim	92220
84	Speculum Slim Long	93784
85	Speculum Mclear	92899



MEDICAL DEVICE AUTHORITY

NO	NAME OF DEVICE	IDENTIFIER
86	Speculum Sclear	99621
87	SPECULUM GR 25 R	96266
88	SPECULUM GR 30 R	96267
89	SPECULUM GR 25	100803
90	SPECULUM GR 30	100804
91	Laser Safety Eyeware	98078
92	Laser Safety Eyeware	99455
93	Laser Safety Eyeware	101081
94	Protective Cap for Patient	68127
95	Protective Cap for Patient	80846
96	Protective Cap for Patient	80847
97	Protective Cap for Patient	85260
98	Footswitch	87593
99	Footswitch	89199
100	SAFETY GOGGLES ER/ND	107211
101	SAFETY GOOGLES ER/ND INNOVATIVE OPTICS 701W.GI1	110732
102	R09-2Gu	97875
103	MicroPilot M100	113014
104	PEN 1.0 D	111408
105	X-Restart	107315
106	TimeWalker AT (M021-5AF/1)	114109
107	HP R11 CE ENG	58619
108	HP R11-7 CE ENG	103690
109	HP PS03X CE ENG	100273
110	HP PS03X-7 CE ENG	103478
111	HP R04-Ti CE ENG	82670



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NO	NAME OF DEVICE	IDENTIFIER
112	HP FS01 CE ENG	88618
113	HP R08-Ti CE ENG	68276
114	HP R02-C CE ENG	69081
115	HP R14-C CE ENG	69084
116	HP HC14-NS CE ENG	95156
117	HP HC14-NE CE ENG	103611
118	X-Restart	107315
119	G-Runner	96381
120	GA Adapter	88925
121	GC Adapter	88928
122	Speculum Standard	88920
123	Speculum Slim	92220
124	Speculum Slim Long	93784
125	Speculum Mclear	92899
126	Speculum Sclear	99621
127	SPECULUM GR 25 R	96266
128	SPECULUM GR 30 R	96267
129	SPECULUM GR 25	100803
130	SPECULUM GR 30	100804
131	GENOVA	95969
132	HP MarcCo CE ENG	NA
133	HP MARCCO S CE ENG	104563
134	HP MARCCO M CE ENG	104283
135	HP MARCCO L CE ENG	104560
136	HP R27-C CE ENG	89672
137	HP R30 CE ENG	63302



MEDICAL DEVICE AUTHORITY

NO	NAME OF DEVICE	IDENTIFIER
138	HP R33-T CE ENG	93457
139	HP R30Y CE ENG	103304
140	MATRIXVIEW TW	109329
141	Laser Safety Eyeware	98078
142	Laser Safety Eyeware	99455
143	Laser Safety Eyeware	101081
144	Protective Cap for Patient	68127
145	Protective Cap for Patient	80846
146	Protective Cap for Patient	80847
147	Protective Cap for Patient	85260
148	Footswitch	87593
149	Footswitch	89199
150	SAFETY GOGGLES ER/ND	107211
151	SAFETY GOGGLES ER/ND INNOVATIVE OPTICS 701W.GI1	110732
152	R09-2Gu	97875
153	MicroPilot M100	113014
154	PEN 1.0 D	111408



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