



DEVICE DETAILS

NAME OF DEVICE	STARWALKER
ESTABLISHMENT NAME	VENUSYS MEDICAL SDN BHD
ROLE OF ESTABLISHMENT	AUTHORIZED REPRESENTATIVE
REGISTRATION NO	GC867531130918
BRAND NAME	FOTONA
MEDICAL DEVICE CATEGORY	MD 1402 - Devices utilising non-ionizing radiation
DEVICE GROUPING TYPE	FAMILY
DEVICE DESCRIPTION	STARWALKER FEATURES 12 LASER TREATMENT MODES OPERATING AT 4 COMPLEMENTARY LASER WAVELENGTHS.BASED ON REVOLUTIONARY ASP (ADAPTIVE STRUCTURED PULSE) TECHNOLOGY, STARWALKER IS CAPABLE OF DELIVERING UP TO NA UNPRECEDENTED 10 J OF Q-SWITCHED ENERGY IN ONE GIANT STRUCTURED MAQX (MODULATED ACOUSTICS Q-SWITCHED) PULSE. THE UNIQUE MAQX HIGH ENERGY CAPABILITY OF STARWALKER ENABLES THE GENERATION OF A HIGHER ENERGY PHOTOACOUSTIC EFFECT AT THE TREATMENT SITE, LEADING TO MORE EFFECTIVE AND FASTER TREATMENTS. ADDITIONALLY, WITH HIGH MAQX ENERGIES, LARGER SPOTSIZES CAN BE USED RESULTING IN MORE HOMOGENOUS TREATMENTS OF EVEN DEEPER LYING SKIN PIGMENTS, AND THEREFORE WITH REDUCED RISK OF UNWANTED SIDE EFFECTS.
DEVICE INTENDED PURPOSE	FOTONA STARWALKER LASER SYSTEM AND ITS ACCESSORIES ARE INTENDED FOR TATTOO REMOVAL, TREATMENT OF PIGMENTED AND VASCULAR LESIONS, SURGICAL AND AESTHETIC APPLICATIONS REQUIRING SELECTIVE PHOTOTHERMOLYSIS OF TARGET CHROMOPHORES IN SOFT TISSUE, AND INCISION/EXCISION, ABLATION AND VAPORIZATION OF SOFT TISSUE IN GENERAL DERMATOLOGY.
VALIDITY DATE OF REGISTRATION	11/10/2023 - 10/10/2028

LIST OF DEVICE

NO	NAME OF DEVICE	IDENTIFIER
1	StarWalker M031-3A/2 MAQX	98616
2	StarWalker M031-3A/2 QX	99172
3	StarWalker M031-3A/2 PQX	104593
4	StarWalker M031-3A/2 PICO Pro	114437
5	Footswitch LW	87593

NO	NAME OF DEVICE	IDENTIFIER
6	Footswitch wireless LW	89199
7	FS 20A d	96027
8	FS 20B d	98738
9	FS 50 d	96028
10	FS 50B d	98739
11	R 28 d	96033
12	R 29 d	92167
13	R 58 d	96035
14	R 585 d	95879
15	R 650 d	95861
16	Skin Cooling system CRYO 6	75957
17	Safety Goggles 1064 IR LB8 + 2940 DI LB4 212	98078
18	Patient Laser Goggle 214	99455
19	Handpiece HP Black/Green CE ENG	104200
20	Handpiece Duo	104207
21	Handpiece Black F5	104255
22	Handpiece Black F9	104254
23	Handpiece Green F5	104256
24	Spacer TUBE FS	103785
25	Spacer TUBE BLACK GREEN	104252
26	Handpiece MovIT	111346
27	Handpiece MovIT High	111347
28	Handpiece MovIT QX	110834
29	Handpiece MovIT High QX	110835
30	Handpiece Leo	113669
31	Handpiece Yellow Lase	114048

NO	NAME OF DEVICE	IDENTIFIER
32	Handpiece Red Lase	114047
33	Handpiece Leo QX	115877
34	Handpiece Yellow Lase QX	114868
35	Handpiece Red Lase QX	114867
36	Handpiece Black/Green Beam	114134
37	SAFETY GOGGLES 650 UNIVET (WIDE FRAME)	115894
38	SAFETY GOGGLES 650 UNIVET (NARROW FRAME)	115895
39	SAFETY GOGGLES IR LB8 + M LB10 @ 1064 NM + 532 NM BIG FRAME	102744
40	SAFETY GOGGLES IR LB8 + M LB10 @ 1064 NM + 532 NM SMAL FRAME	102745
41	SAFETY GOGGLES ER/ND	107211
42	SAFETY GOOGLES ER/ND INNOVATIVE OPTICS 701W.GI1.	110732
43	OCULAR LASER SHIELD-PAIR(INTERIOR)	68127
44	EYE PROTECTION SMALL	80846
45	EYE PROTECTION MEDIUM	80847
46	EYE PROTECTION LARGE	85260
47	SAFETY GOGGLES KTP	110214
48	SAFETY GOGGLES 585 LASERSCHUTZ	115747