



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 Fotona QX Max M031-3A/2 MAQX	99166
2	StarWalker Fotona QX Max M031-3A/2 QX	99167
3	StarWalker Fotona PQX M031-3A/2 PQX	104593
4	Footswitch LW	87593
5	Footswitch wireless LW	89199

NO	NAME OF DEVICE	IDENTIFIER
6	FS 20 d	96026
7	FS 20A d	96027
8	FS 20B d	98738
9	FS 20C d	98740
10	FS 50 d	96028
11	FS 50B d	98739
12	R 28 d	96033
13	R 29 d	92167
14	R 58 d	96035
15	R 585 d	95879
16	R 650 d	95861
17	Skin Cooling system CRYO 6	75957
18	Safety Goggles ER/ND, Univet (Large Frame) 212	64341
19	Safety Goggles ER/ND, Univet (Small Frame) 212	97873
20	Safety Goggles 1064 IR LB8 + 2940 DI LB4 212	98078
21	Safety Goggles Honeywell IRM LB8, 1064+532 NM 175	97123
22	Safety Goggles ND+KTP 160	93479
23	Safety Goggles 585NM+650NM DYE (Large Frame) 184	97874
24	Safety Goggles 585NM+650NM DYE (Small Frame) 184	90413
25	Patient Laser Goggle 214	99455
26	Handpiece HP Black/Green CE ENG	104200
27	Handpiece Duo	104207
28	Handpiece Black F5	104255
29	Handpiece Black F9	104254
30	Handpiece Green F5	104256
31	Spacer TUBE FS	103785

NO	NAME OF DEVICE	IDENTIFIER
32	Spacer TUBE BLACK GREEN	104252

