



DEVICE DETAILS

NAME OF DEVICE	XS DYNAMIS
ESTABLISHMENT NAME	VENUSYS MEDICAL SDN BHD
ROLE OF ESTABLISHMENT	AUTHORIZED REPRESENTATIVE
REGISTRATION NO	GC7320085916
BRAND NAME	FOTONA
MEDICAL DEVICE CATEGORY	MD 1202 - Imaging devices utilising non-ionizing radiation
DEVICE GROUPING TYPE	SYSTEM
DEVICE DESCRIPTION	THIS DEVICE IS A MEDICAL LASER DEVICE WHICH CONSISTS OF ER:YAG LASER WITH A WAVELENGTH OF 2940NM. WITH ADVANCED TREATMENT ATTRIBUTES AND FULLY CUSTOMIZABLE SETTINGS, FOTONAâ€™S XS DYNAMIS OFFERS TRUE 3RD GENERATION ER:YAG LASER SKIN RESURFACING. THE XS DYNAMIS REPRESENTS A COMPLETE REJUVENATION SOLUTION. ITS FUNCTIONS RANGE FROM SUPERFICIAL TO DEEP PEELS, FROM NON-ABLATIVE TO FULLY ABLATIVE AND FROM FULL-FIELD TO FRACTIONAL RESURFACING.
DEVICE INTENDED PURPOSE	THIS MEDICAL LASER DEVICES CAN BE USED FOR MANY DIFFERENT APPLICATION IN DERMATOLOGY, GYNECOLOGY AND SURGERY. IT IS APPLICABLE ON ANY LESION WHICH NEEDS TO BE ABLATE OR CUT AS WELL AS COLLAGEN STIMULATION. INDICATIONS INCLUDE SUPERFICIAL SKIN PIGMENTATION, WRINKLES, SKIN TAGS, AND STRESS URINARY INCONTINENCE AND ETC.
VALIDITY DATE OF REGISTRATION	10/11/2021 - 09/11/2026

LIST OF DEVICE

NO	NAME OF DEVICE	IDENTIFIER
1	F-22 Er:Yag Scanner (F-runner)	85776
2	S-22 Er:YAG scanner (S-runner)	85778
3	PS01	83247
4	PS02	83244
5	PS03 with / without G-Set	83977
6	PS03-A	91768
7	PS05	93943

NO	NAME OF DEVICE	IDENTIFIER
8	PS05-9 with / without G-Set	93944
9	R04-Ti	83246
10	R04F	70942
11	R08-Ti	70935
12	R09-2	70836
13	R09-3	70838
14	R09-2G	70837
15	R11 with / without G-Set	70945
16	R11-9 with / without G-Set	93945
17	FS01	89457
18	Speculum Standard	92408 - part of 90368 and 92386
19	Speculum Slim	92409 - part of 93686 and 92386
20	Speculum Slim Long	93784 - part of 94444
21	Speculum Mclear	92899 - part of 94445
22	Speculum Sclear	924446 - part of 94638 and 94764
23	GC Adapter Assembly	88928 - part of 90368, 92386, 94638
24	GA Adapter Assembly	88925 - part of 90368, 92386, 94638