



DEVICE DETAILS

NAME OF DEVICE	XP SERIES
ESTABLISHMENT NAME	VENUSYS MEDICAL SDN BHD
ROLE OF ESTABLISHMENT	AUTHORIZED REPRESENTATIVE
REGISTRATION NO	GC8237523616
BRAND NAME	FOTONA
MEDICAL DEVICE CATEGORY	MD 1202 - Imaging devices utilising non-ionizing radiation
DEVICE GROUPING TYPE	FAMILY
DEVICE DESCRIPTION	THIS DEVICE IS A MEDICAL SURGICAL LASER OR AESTHETIC LASER CONSIST OF A WAVELENGTH 1064NM, A LONG-PULSED ND:YAG LASER WHICH IS MEANT FOR APPLICATIONS IN DERMATOLOGY AND GYNECOLOGY.
DEVICE INTENDED PURPOSE	THIS MEDICAL DEVICE IS USED IN DERMATOLOGY AND GYNECOLOGY TREATMENT SUCH AS VASCULAR LESIONS AND VAGINAL TIGHTENING.
VALIDITY DATE OF REGISTRATION	14/05/2021 - 13/05/2026

LIST OF DEVICE

NO	NAME OF DEVICE	IDENTIFIER
1	FOTONA XP DYNAMIS	85992 & 92730 (Touch Screen)
2	FOTONA XP SPECTRO	87005 & 92732 (Touch Screen)