



DEVICE DETAILS

NAME OF DEVICE	SP SERIES
ESTABLISHMENT NAME	VENUSYS MEDICAL SDN BHD
ROLE OF ESTABLISHMENT	AUTHORIZED REPRESENTATIVE
REGISTRATION NO	GC1999023716
BRAND NAME	FOTONA
MEDICAL DEVICE CATEGORY	MD 1202 - Imaging devices utilising non-ionizing radiation
DEVICE GROUPING TYPE	FAMILY
DEVICE DESCRIPTION	MEDICAL LASER FOR APPLICATIONS IN DERMATOLOGY, GYNECOLOGY AND SURGERY
DEVICE INTENDED PURPOSE	MEDICAL LASER FOR APPLICATIONS IN DERMATOLOGY, GYNECOLOGY AND SURGERY
VALIDITY DATE OF REGISTRATION	14/05/2021 - 13/05/2026

LIST OF DEVICE

NO	NAME OF DEVICE	IDENTIFIER
1	FOTONA SP DYNAMIS	85996 & 92729 (Touch Screen)
2	FOTONA SP SPECTRO	87006 & 92731 (Touch Screen)