



DEVICE DETAILS

NAME OF DEVICE	SKYPULSE
ESTABLISHMENT NAME	VENUSYS MEDICAL SDN BHD
ROLE OF ESTABLISHMENT	AUTHORIZED REPRESENTATIVE
REGISTRATION NO	GC6239524-179855
BRAND NAME	FOTONA
MEDICAL DEVICE CATEGORY	MD 1402 - Devices utilising non-ionizing radiation
DEVICE GROUPING TYPE	FAMILY
DEVICE DESCRIPTION	The SkyPulse laser system family consists of two different versions: <ul style="list-style-type: none"> • SkyPulse M321-A abbreviated as SkyPulse Versa / Endo Pro which has XS-A Er:YAG laser module and offers water spray for cooling the treated area or Endo Plus which can have XS- A or XSC Er:YAG laser module and also offers water spray for cooling the treated area. • SkyPulse M321-B abbreviated as SkyPulse Endo which has XSB Er:YAG laser module and does not offer water spray for cooling the treated area.
DEVICE INTENDED PURPOSE	The device and its accessories are intended to be used in dentistry, aesthetics, dermatology, ENT, surgery and pain management.
VALIDITY DATE OF REGISTRATION	17/08/2024 - 16/08/2029

LIST OF DEVICE

NO	NAME OF DEVICE	IDENTIFIER
No results found.		