

DEVICE DETAILS

NAME OF DEVICE	QX MAX
ESTABLISHMENT NAME	VENUSYS MEDICAL SDN BHD
ROLE OF ESTABLISHMENT	AUTHORIZED REPRESENTATIVE
REGISTRATION NO	GC8425037716
BRAND NAME	FOTONA
MEDICAL DEVICE CATEGORY	MD 1402 - Devices utilising non-ionizing radiation
DEVICE GROUPING TYPE	SYSTEM
DEVICE DESCRIPTION	THE FOTONA QX MAX LASER SYSTEMS INCORPORATE THE FOLLOWING LASER SOURCES: -Q-SWITCHED ND:YAG LASER, WITH A WAVELENGTH OF 1064 NM -ACCELERA (ACC) PULSE ND:YAG, WITH A WAVELENGTH OF 1064 NM -FREQUENCY-DOUBLED Q-SWITCHED ND:YAG LASER (OR Q-SWITCHED, KTP), WITH A WAVELENGTH OF 532 NM -BEAM CONVERTER R650, WITH A WAVELENGTH OF 650NM -BEAM CONVERTER R585, WITH A WAVELENGTH OF 585NM -AIMING BEAM DIODE LASER, WITH A WAVELENGTH OF 650 NM
DEVICE INTENDED PURPOSE	FOTONA QX MAX 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	11/07/2021 - 10/07/2026

LIST OF DEVICE

NO	NAME OF DEVICE	IDENTIFIER
1	Fotona QX Max laser (Main Body)	82398
2	Footswitch assembly	68356
3	Footswitch assembly	82665
4	HP R28	82922
5	HP R-HX	90025
6	HP FS-20	93759
7	HP FS-20A	93760

NO	NAME OF DEVICE	IDENTIFIER
8	HP FS-50	93758
9	HP R650	84367
10	HP R585	84368
11	Safety goggles	93479



MEDICAL DEVICE AUTHORITY