



## DEVICE DETAILS

<b>NAME OF DEVICE</b>	QX MAX
<b>ESTABLISHMENT NAME</b>	VENUSYS MEDICAL SDN BHD
<b>ROLE OF ESTABLISHMENT</b>	AUTHORIZED REPRESENTATIVE
<b>REGISTRATION NO</b>	GC8425037716
<b>BRAND NAME</b>	FOTONA
<b>MEDICAL DEVICE CATEGORY</b>	MD 1402 - Devices utilising non-ionizing radiation
<b>DEVICE GROUPING TYPE</b>	SYSTEM
<b>DEVICE DESCRIPTION</b>	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
<b>DEVICE INTENDED PURPOSE</b>	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.
<b>VALIDITY DATE OF REGISTRATION</b>	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

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



**MEDICAL DEVICE AUTHORITY**