



DEVICE DETAILS

NAME OF DEVICE	DYNAMIS SPECTRO
ESTABLISHMENT NAME	VENUSYS MEDICAL SDN BHD
ROLE OF ESTABLISHMENT	AUTHORIZED REPRESENTATIVE
REGISTRATION NO	GC4117726-223121
BRAND NAME	FOTONA
MEDICAL DEVICE CATEGORY	MD 1202 - Imaging devices utilising non-ionizing radiation
DEVICE GROUPING TYPE	FAMILY
DEVICE DESCRIPTION	<p>The Fotona Dynamis and Spectro line of laser systems incorporate lasers that operate in the invisible near- and mid-infrared ranges of the electromagnetic spectrum, as well as an aiming beam laser that operates in the visible range. The unique Variable Square Pulse (VSP) Technology integrated in Fotona's laser systems allows ultimate control of laser energy and laser pulse length. This ensures treatment precision, patient comfort, safety and ease-of-use in all treatments. There are three basic models in the Fotona Dynamis line (M021-4AF/3, M002-2A, M001-12F), which are available in different variants, each incorporating a different combination of laser sources and graphical user interface possibilities: SP Dynamis (in some markets known as Fotona SP Plus); M021-4AF/3: • Er:YAG laser, with a wavelength of 2940 nm • Nd:YAG laser, with a wavelength of 1064 nm XS Dynamis (in some markets known as Dualis XS); M002-2A: • Er:YAG laser, with a wavelength of 2940 nm XP Dynamis (in some markets known as Dualis XP Plus); M001-12F: • Nd:YAG laser with a wavelength of 1064 nm FotonaSmooth XS (XS Dynamis dedicated for applications in gynecology); M002-2A: • Er:YAG laser with a wavelength of 2940 nm FotonaSmooth SP+ (SP Dynamis dedicated for applications in gynecology); M021-4AF/3: • Er:YAG laser, with a wavelength of 2940 nm • Nd:YAG laser, with a wavelength of 1064 nm SP Dynamis (Dynamis Max) with a bigger touchscreen, DMC cooling and/or vacuum pump module; M021-4AF/3: • Er:YAG laser, with a wavelength of 2940 nm • Nd:YAG laser, with a wavelength of 1064 nm The Fotona Spectro line has one basic model (M021-4AF/3) available in two variants, each incorporating a different combination of laser sources and graphical user interface possibilities: SP Spectro (in some markets known as Dualis SP II); M021-4AF/3: • Er:YAG laser, with a wavelength of 2940 nm • Nd:YAG laser, with a wavelength of 1064 nm FotonaSmooth SP (SP Spectro dedicated for applications in gynecology); M021-4AF/3: • Er:YAG laser, with a wavelength of 2940 nm • Nd:YAG laser, with a wavelength of 1064 nm The aiming laser in all models is a semiconductor diode laser with a wavelength of 650 nm. Both treatment laser types are pulsed solid-state lasers that generate high-energy concentrated light with homogeneous treatment spot, which may cause serious injury if used improperly. For this reason, the operator must carefully read the manual before attempting to operate the device.</p>
DEVICE INTENDED PURPOSE	Dynamis Spectro Surgical Lasers are intended to be used in the fields of dentistry, aesthetics, dermatology, gynaecology and urology, ENT, surgery and pain management.

VALIDITY DATE OF REGISTRATION	19/01/2026 - 18/01/2031
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LIST OF DEVICE

NO	NAME OF DEVICE	IDENTIFIER
No results found.		



MEDICAL DEVICE AUTHORITY