



DEVICE DETAILS

NAME OF DEVICE	STARFORMER FAMILY
ESTABLISHMENT NAME	VENUSYS MEDICAL SDN BHD
ROLE OF ESTABLISHMENT	AUTHORIZED REPRESENTATIVE
REGISTRATION NO	GB3862525-210390
BRAND NAME	FOTONA
MEDICAL DEVICE CATEGORY	MD 1103 - Devices for stimulation or inhibition
DEVICE GROUPING TYPE	FAMILY
DEVICE DESCRIPTION	Fotona StarFormer is device which is used for muscle strengthening on areas of glutes, abdomen, hamstring area, arms and pelvic floor using High Intensity Magnetic Stimulation (HIMS). Fotona StarFormer will provide a pulsed magnetic field that will through its effect on muscles has been scientifically found that the technology of HIMS will result in increased muscle mass after multiple treatments on the same target location. During the treatment, the patient will either be lying on the therapeutic table or will be sitting on a chair. The procedure will last for about 30 minutes and can be performed for alternate days in a week. Do note that the treatment is non-invasive and the effectiveness of the treatment is not affected by clothes on the patient's body. The Fotona StarFormer magnetic system family consists of: 1) model M008-3T with commercial names - StarFomer - TightWave 2) model M008-5T with commercial name - IntimaWave
DEVICE INTENDED PURPOSE	The StarFormer Family of devices and their accessories are intended for magnetic stimulation in the field of Aesthetics, Urology, Gynecology, Rehabilitation, Physiotherapy, and Pain Management.
VALIDITY DATE OF REGISTRATION	04/09/2025 - 03/09/2030

LIST OF DEVICE

NO	NAME OF DEVICE	IDENTIFIER
1	STARFORMER	113037
2	STARFORMER APPLICATOR LARGE	105770
3	STARFORMER APPLICATOR RADIAL LARGE	105875
4	STARFORMER APPLICATOR RADIAL XLARGE	111352
5	STARFORMER INTIMAWAVE CHAIR	105780
6	INTIMAWAVE	108078

NO	NAME OF DEVICE	IDENTIFIER
7	STARFORMER INTIMAWAVE CHAIR	105780



MEDICAL DEVICE AUTHORITY