



DEVICE DETAILS

NAME OF DEVICE	MAGNETO THERAPY
ESTABLISHMENT NAME	VENUSYS MEDICAL SDN BHD
ROLE OF ESTABLISHMENT	AUTHORIZED REPRESENTATIVE
REGISTRATION NO	GB2250521-79528
BRAND NAME	FOTONA STARFORMER
MEDICAL DEVICE CATEGORY	MD 1400 - DEVICES FOR RADIATION THERAPY AND THERMO THERAPY
DEVICE GROUPING TYPE	FAMILY
DEVICE DESCRIPTION	<p>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 Both variants are the same in terms of technical characteristics, basic safety and essential performance, but they differ at two areas, (number of channels and accessories) as below ; 1) StarFormer and TightWave have 4 channels and all accessories. 2) IntimaWave only have 2 channels and only have starformer intimawave chair accessories.</p>
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	26/11/2021 - 25/11/2026

LIST OF DEVICE

NO	NAME OF DEVICE	IDENTIFIER
1	STARFORMER	M008-3T
2	HP STARFORMER APPLICATOR LARGE	106232
3	HP STARFORMER APPLICATOR RADIAL LARGE	106365
4	STARFORMER INTIMAWAVE CHAIR	105780

NO	NAME OF DEVICE	IDENTIFIER
5	FOTONA STARFORMER ARM	105779
6	TIGHTWAVE	M008-3T
7	HP STARFORMER APPLICATOR LARGE	106232
8	HP STARFORMER APPLICATOR RADIAL LARGE	106365
9	STARFORMER INTIMAWAVE CHAIR	105780
10	FOTONA STARFORMER ARM	105779
11	INTIMAWAVE	M008-5T
12	STARFORMER INTIMAWAVE CHAIR	105780
13	FOTONA STARFORMER ARM	105779



MEDICAL DEVICE AUTHORITY