

DEVICE DETAILS

NAME OF DEVICE	ULTRAFORMER MPT
ESTABLISHMENT NAME	ANDAMAN MEDICAL BRIDGE SDN. BHD.
ROLE OF ESTABLISHMENT	AUTHORIZED REPRESENTATIVE
REGISTRATION NO	GC9728724-174234
BRAND NAME	NOT APPLICABLE
MEDICAL DEVICE CATEGORY	MD 1100 - GENERAL ACTIVE MEDICAL DEVICES
DEVICE GROUPING TYPE	SYSTEM
DEVICE DESCRIPTION	ULTRAFORMER MPT is an assembly of devices designed to produce and control the delivery of high heat to the body using ultrasonic energy for the intracorporeal treatment of skin lifting and tightening. Higher ultrasound frequencies have more superficial tissue effects and lower frequencies have deeper tissue effects. When ultrasound waves are micro-focused to a point in living tissue, molecular vibration results and heat is generated creating well-defined thermal injury zones at predetermined depths while leaving the surrounding tissue unaffected. The feature directs acoustic waves to the treatment area. This acoustic energy heats tissue as a result of frictional losses during energy absorption, producing discrete points of coagulation.
DEVICE INTENDED PURPOSE	The ULTRAFORMER MPT is a non-invasive therapeutic device for skin lifting and tightening. The information regarding the categories of users: Education: Medical doctor Knowledge: Medical knowledge of the skin Language understanding: English or languages offered in the instruction for use.
VALIDITY DATE OF REGISTRATION	30/05/2024 - 29/05/2029

LIST OF DEVICE

NO	NAME OF DEVICE	IDENTIFIER
1	ULTRAFORMER MPT	UF4-M400
2	Handpiece	ULTRA BOOSTER
3	Handpiece	ULTRA F
4	Cartridge	ULTRAFOMER MPT 1.5
5	Cartridge	ULTRAFORMER MPT 3.0
6	Cartridge	ULTRAFORMER MPT 2.0
7	Cartridge	ULTRAFORMER MPT 4.5

NO	NAME OF DEVICE	IDENTIFIER
8	Cartridge	ULTRAFORMER MPT 6.0
9	Cartridge	ULTRAFORMER MPT 9.0
10	Cartridge	ULTRAFORMER MPT 13.0
11	Cartridge	DERMA BOOSTER 1.5
12	Cartridge	CELL UP BOOSTER 3.0
13	Cartridge	LINE UP BOOSTER 4.5
14	AC Power Cable	5620-00001-001
15	Foot Switch	7438-00361-001



MEDICAL DEVICE AUTHORITY