



DEVICE DETAILS

NAME OF DEVICE	ULThERA SYSTEM
ESTABLISHMENT NAME	T T MEDICAL MANAGEMENT SDN BHD
ROLE OF ESTABLISHMENT	AUTHORIZED REPRESENTATIVE
REGISTRATION NO	GC46632715118
BRAND NAME	ULThERA
MEDICAL DEVICE CATEGORY	MD 1402 - Devices utilising non-ionizing radiation
DEVICE GROUPING TYPE	SYSTEM
DEVICE DESCRIPTION	The Ulthera System integrates the capabilities of ultrasound imaging with those of ultrasound therapy. The imaging feature allows the user to visualize the skin and sub-dermal regions of interest before treatment. It also allows the user to assure proper skin contact in order to deliver the energy at desired depths. The therapy 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. The Ulthera System consists of three primary components: the control unit with integrated touchscreen, the handpiece with cable, and interchangeable transducers.
DEVICE INTENDED PURPOSE	The Ulthera System is intended for lifting and sculpting of skin by way of the deposition of micro-focused ultrasound energy at depths between 1.5mm and 4.5 mm beneath the skin. Deposition of ultrasound energy results in a change to the physiology, resulting in stimulation of new collagen and elastin as part of the healing process. The Ulthera System is also intended for the treatment of Axillary Hyperhidrosis by way of the deposition of the micro-focused ultrasound energy at depths between 3.0 mm and 4.5 mm beneath the skin, targeting the depth at which sweat glands reside. Coagulation takes place in tissue located at the dermal hypodermal interface where the sweat glands reside using a surface contact applicator. Sweat glands are destroyed during coagulation. The Ulthera System is indicated for: <ul style="list-style-type: none"> • Use for non-invasive dermatological sculpting and lifting of the dermis o Upper Face o Lower Face o Neck o Décolleté • Non-invasive treatment of Axillary Hyperhidrosis
VALIDITY DATE OF REGISTRATION	28/02/2023 - 27/02/2028

LIST OF DEVICE

NO	NAME OF DEVICE	IDENTIFIER
1	Ulthera® Control Unit	UC-1
2	Ulthera® DeepSEE® Handpiece	UH-2
3	Ulthera® DeepSEE® Transducer DS 7-3.0	UT-1

NO	NAME OF DEVICE	IDENTIFIER
4	Ulthera® DeepSEE® Transducer DS 7-3.0N	UT-1N
5	Ulthera® DeepSEE® Transducer DS 4-4.5	UT-2
6	Ulthera® DeepSEE® Transducer DS 7-4.5	UT-3
7	Ulthera® DeepSEE® Transducer DS 10-1.5	UT-4
8	Ulthera® DeepSEE® Transducer DS 10-1.5N	UT-4N
9	Ulthera® System Access Key	UK-1
10	Ulthera® System Cart	UR-1



MEDICAL DEVICE AUTHORITY