



## DEVICE DETAILS

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| <b>NAME OF DEVICE</b>                | ULThera SYSTEM  |
| <b>ESTABLISHMENT NAME</b>            | T T MEDICAL MANAGEMENT SDN BHD  |
| <b>ROLE OF ESTABLISHMENT</b>         | AUTHORIZED REPRESENTATIVE   |
| <b>REGISTRATION NO</b>               | GC46632715118   |
| <b>BRAND NAME</b>                    | ULThera   |
| <b>MEDICAL DEVICE CATEGORY</b>       | MD 1402 - Devices utilising non-ionizing radiation  |
| <b>DEVICE GROUPING TYPE</b>          | SYSTEM  |
| <b>DEVICE DESCRIPTION</b>            | 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.  |
| <b>DEVICE INTENDED PURPOSE</b>       | 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"> <li>• Use for non-invasive dermatological sculpting and lifting of the dermis <ul style="list-style-type: none"> <li>o Upper Face</li> <li>o Lower Face</li> <li>o Neck</li> <li>o Décolleté</li> </ul> </li> <li>• Non-invasive treatment of Axillary Hyperhidrosis</li> </ul> |
| <b>VALIDITY DATE OF REGISTRATION</b> | 28/02/2023 - 27/02/2028   |

## LIST OF DEVICE

| NO                | NAME OF DEVICE | IDENTIFIER |
|-------------------|----------------|------------|
| No results found. |                |            |