



Australian Government

Department of Health and Aged Care
Therapeutic Goods Administration

Australian Register of Therapeutic Goods Certificate

Issued to

Emergo Asia Pacific Pty Ltd T/a Emergo Australia

for approval to supply

Emergo Asia Pacific Pty Ltd T/a Emergo Australia - High Intensity Focused Ultrasound - Ultrasonic skin contouring system

ARTG Identifier	413442
ARTG Start Date	13/07/2023
Product Category	Medical Device Included Class IIb
GMDN	62436
GMDN Term	Ultrasonic skin contouring system
Intended Purpose	The High Intensity Focused Ultrasound is a non-invasive therapeutic device for the treatment of ptosis, treatment of skin laxity using the principle of coagulation and necrosis.

Manufacturer Details	Address	Certificate number(s)
IDS Ltd	194 Simgung-ro Gwangtan-myeon Paju-si , Gyeonggi-do , 10952 Korea - Republic of	DV-2023-MC-11352-1

ARTG Standard Conditions

The above Medical Device Included Class IIb has been entered on the Register subject to the following conditions:

- The inclusion of the kind of device in the ARTG is subject to compliance with all conditions placed or imposed on the ARTG entry. Refer Part 4-5, Division 2 (Conditions) of the Therapeutic Goods Act 1989 and Part 5, Division 5.2 (Conditions) of the Therapeutic Goods (Medical Devices) Regulations 2002 for relevant information.
- Breaching conditions of the inclusion related to the device of the kind may lead to suspension or cancellation of the ARTG entry; may be a criminal offence; and civil penalties may apply.

Products Covered by This Entry

1. High Intensity Focused Ultrasound - Ultrasonic skin contouring system

Product Specific Conditions

No specific conditions have been recorded against this entry.

Therapeutic Goods Administration
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