



Australian Government

Department of Health
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 - Dermatological optical coherence tomography system

ARTG Identifier	297159
ARTG Start date	4/12/2017
Product Category	Medical Device Included Class IIa
GMDN	58074
GMDN Term	Dermatological optical coherence tomography system
Intended Purpose	The device is indicated for use in the two-dimensional, cross-sectional, real-time imaging of external tissues of the human body. This indicated use allows imaging of tissue microstructure including skin, and enables detection and display of regions within the scanned area that are in motion (Dynamic OCT) to aid trained and competent clinicians in their assessment of a patient's clinical conditions.

Manufacturer Details	Address	Certificate number(s)
Michelson Diagnostics Ltd	Ground Floor Eclipse House Eclipse Park Sittingbourne Road Maidstone, Kent, ME14 3EN United Kingdom	DV-2017-MC-18208-1

ARTG Standard Conditions

The above Medical Device Included Class IIa 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. Dermatological optical coherence tomography system

Product Specific Conditions

No specific conditions have been recorded against this entry.

Therapeutic Goods Administration
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