



Australian Government

Department of Health  
Therapeutic Goods Administration

# Australian Register of Therapeutic Goods Certificate

Issued to

**CORTEX HEALTH PTY LTD**

for approval to supply

## **CORTEX HEALTH PTY LTD - Echolight - Ultrasound system, bone absorptiometer**

<b>ARTG Identifier</b>	344830
<b>ARTG Start Date</b>	28/09/2020
<b>Product Category</b>	Medical Device Included Class IIa
<b>GMDN</b>	40779
<b>GMDN Term</b>	Ultrasound system, bone absorptiometer
<b>Intended Purpose</b>	Echolight devices (EchoStation, EchoS, EchoHybrid) are all designed to accurately measure bone mineral density (BMD). These devices use patented Radiofrequency Echographic Multi Spectrometry (REMS), highly specific ultrasound technology. The intended use is as a screening &/or diagnostic tool to determine BMD and give the clinician a T-Score and Z-score. The generated findings & report will determine whether the patient has normal BMD or has any degree of osteopenia or osteoporosis according to their specific readings vs matched age controls.

Manufacturer Details	Address	Certificate number(s)
Echolight SpA	Via Provinciale Lecce-Mpnteroni Snc-Campus , Ecotekne Lecce LE , 73100 Italy	DV-2020-MC-27396-2

### 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. Echolight - Ultrasound system, bone absorptiometer

### Product Specific Conditions

No specific conditions have been recorded against this entry.