



Australian Government
Department of Health
Therapeutic Goods Administration

Australian Register of Therapeutic Goods Certificate

Issued to

Sonoray Pty Ltd

for approval to supply

Sonoray Pty Ltd - Stimulator, magnetic

ARTG Identifier	148142
ARTG Start Date	5/12/2007
Product Category	Medical Device Included Class IIa
GMDN	36902
GMDN Term	Psycho-cognitive electromagnetic stimulator
Intended Purpose	Treatment of Major Depressive Disorder in adult patients who have failed to achieve satisfactory improvement from two prior antidepressant medications, at or above the minimal effective dose and duration in the current episode; and as an adjunct for the treatment of adult patients suffering from Obsessive-Compulsive Disorder (OCD), Comorbid Anxiety; and for the treatment of psychoactive substance use disorders (PSUD) caused by drugs with stimulatory effect on brain function in adult patients.

Manufacturer Details	Address	Certificate number(s)
Tonica Elektronik A/S	Lucernemarken 15 , Farum , 3520 Denmark	DV-20071113-MC-049796-11

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. Stimulator, magnetic

Product Specific Conditions

- No specific conditions have been recorded against this entry.

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