



Australian Government
Department of Health
Therapeutic Goods Administration

Record Summary	356311	ACRA Regulatory Services Pty Ltd - Subdermal needle electrode
Sponsor	ACRA Regulatory Services Pty Ltd	
Therapeutic Type	Medical Device	
Product Category	Included Class IIa	
ARTG Start Date	5/03/2021	
Postal Address	7/84 Poinciana Avenue, Tewantin, QLD, 4565 Australia	
Billing Address	7/84 Poinciana Avenue, Tewantin, QLD, 4565 Australia	
Product Type	Medical Device - Class IIa - Included	
Status	Active	
Approval Area	Medical Devices	

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.

Manufacturers

Name	Address	Certificate number(s)
Technomed Europe	Amerikalaan 71 Maastricht Airport , , 6199 AE Netherlands	DV-2021-MC-00923-1

Products

1 . Subdermal needle electrode

Product Type	Single Device Product	Status	Current
		Effective Date	5/03/2021
GMDN	47714 Subdermal needle electrode		
Functional Description	Not included on record		
Intended Purpose	Single use sterile subdermal needle electrodes are intended to be inserted in the subderma, muscle or nerve tissue to sense bio-electric, EMG or EEG signals distally, and to be connected to EMG/EEG recording equipment		

Variant Information

Device Information

Record Summary

Specific Conditions

No Specific Conditions included on Record

Record Summary