



Australian Government
Department of Health
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry: 355100 ACRA Regulatory Services Pty Ltd - Cable/lead, electromyograph

ARTG entry for Medical Device Included Class 1
Sponsor ACRA Regulatory Services Pty Ltd
Postal Address 7/84 Poinciana Avenue, Tewantin, QLD, 4565
Australia
ARTG Start Date 17/02/2021
Product Category Medical Device Class 1
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
Technomed Europe	Amerikalaan 71 Maastricht Airport, , 6199 AE Netherlands

Products

1 . Cable/lead, electromyograph

Product Type	Single Device Product	Effective Date	17/02/2021
GMDN	35750 Cable/lead, electromyograph		
Intended Purpose	Reusable non-invasive electrode cables are intended to connect electrodes to a recording/ monitoring device for the recording of bio potential signals in EEG, EMG, and nerve conduction studies.		

Specific Conditions

No Specific Conditions included on Record

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