



**Australian Government**  
**Department of Health**  
Therapeutic Goods Administration

## Public Summary

**Summary for ARTG Entry:** 277072 ACRA Regulatory Services Pty Ltd - Electrode, electromyograph

**ARTG entry for** Medical Device Included Class IIa  
**Sponsor** ACRA Regulatory Services Pty Ltd  
**Postal Address** 7/84 Poincina Avenue, Tewantin, QLD, 4565  
Australia  
**ARTG Start Date** 27/06/2016  
**Product Category** Medical Device Class IIa  
**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 . Electrode, electromyograph

<b>Product Type</b>	Single Device Product	<b>Effective Date</b>	27/06/2016
<b>GMDN</b>	11441 Electrode, electromyograph		
<b>Intended Purpose</b>	A Sterile electrical conducting device designed to be inserted transcutaneously into muscle or nerve tissue to detect bioelectrical signal activity. It is a needle like device ( a needle electrode with an electrical connector at the proximal end) that is connected to an electromyograph (EMG) with a dedicated cable /lead. The EMG records the electrical signal and converts them to a readable graph format. This is a single use device		

### Specific Conditions

No Specific Conditions included on Record

© Commonwealth of Australia. This work is copyright. You are not permitted to re-transmit, distribute or commercialise the material without obtaining prior written approval from the Commonwealth. Further details can be found at <http://www.tga.gov.au/about/website-copyright.htm>.

Public Summary