



Australian Government
Department of Health
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry: 108391 AMBU Australia Pty Ltd - Electrode, electromyograph

ARTG entry for Medical Device Included Class IIa
Sponsor AMBU Australia Pty Ltd
Postal Address 2/1 Prosperity Parade, WARRIEWOOD, NSW, 2102
Australia
ARTG Start Date 9/09/2004
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
Ambu AS	Baltorpbakken 13 Ballerup, , DK-2750 Denmark

Products

1 . Electrode, electromyograph

Product Type	Single Device Product	Effective Date	9/09/2004
GMDN	11441 Electrode, electromyograph		
Intended Purpose	For recording bioelectrical signals during an electromyograph		

Specific Conditions

No Specific Conditions included on Record

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