



Australian Government

Department of Health  
Therapeutic Goods Administration

# Australian Register of Therapeutic Goods Certificate

Issued to

**AMBU Australia Pty Ltd**

for approval to supply

**AMBU Australia Pty Ltd - Electrode, <specify>**

**ARTG Identifier** 167606  
**ARTG Start date** 17/12/2009  
**Product Category** Medical Device Included Class 1  
**GMDN** 15578  
**GMDN Term** Electrode, <specify>  
**Intended Purpose** A surface electrode for use in sleep studies, and neurological PSG SEP

Manufacturer Details	Address	Certificate number(s)
Ambu AS	Baltorpbakken 13 Ballerup, , DK-2750 Denmark	

## ARTG Standard Conditions

The above Medical Device Included Class 1 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. Electrode, <specify>

## Product Specific Conditions

- No specific conditions have been recorded against this entry.

Therapeutic Goods Administration  
PO Box 100, Woden ACT 2606 Australia  
Phone: 1800 020 653  
Email: info@tga.gov.au

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