



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, electrocardiograph, single use**

<b>ARTG Identifier</b>	167615
<b>ARTG Start date</b>	17/12/2009
<b>Product Category</b>	Medical Device Included Class 1
<b>GMDN</b>	35035
<b>GMDN Term</b>	Electrode, electrocardiograph, single use
<b>Intended Purpose</b>	A surface electrode intended to allow connection of leads/cables for transmission of electrical signals to an electrocardiogram.

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, electrocardiograph, single use**

### **Product Specific Conditions**

- No specific conditions have been recorded against this entry.

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