

#### 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, neonatal

ARTG Identifier	167611	
ARTG Start date	17/12/2009	
Product Category	Medical Device Included Class 1	
GMDN	17460	
GMDN Term	Electrode, electrocardiograph, neonatal	
Intended Purpose	A surface electrode to conduct electrical impulses to an electrocardiogram. For use in neonates	

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, neonatal

#### **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 ARTG Identifier: 167611 ARTG Start Date: 17/12/2009