



**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 - Subdermal needle electrode

<b>ARTG Identifier</b>	324062
<b>ARTG Start date</b>	26/09/2019
<b>Product Category</b>	Medical Device Included Class IIa
<b>GMDN</b>	47714
<b>GMDN Term</b>	Subdermal needle electrode
<b>Intended Purpose</b>	A corkscrew electrode intended to be placed subdermally during surgery for monitoring, recording and stimulation of bio- and nerve potential signals.

Manufacturer Details	Address	Certificate number(s)
Technomed Europe	Amerikalaan 71 Maastricht Airport, , 6199 AE Netherlands	DV-2019-MC-15097-1

### ARTG Standard Conditions

The above Medical Device Included Class IIa 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. Subdermal needle electrode

### Product Specific Conditions

No specific conditions have been recorded against this entry.

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