



**Australian Government**  
**Department of Health**  
Therapeutic Goods Administration

## Public Summary

**Summary for ARTG Entry:** 311383 Symbiotic Devices Pty Ltd - Subdermal needle electrode

**ARTG entry for** Medical Device Included Class IIa  
**Sponsor** Symbiotic Devices Pty Ltd  
**Postal Address** Suite 138 / 245 Thomas Street, DANDENONG, VIC, 3175  
Australia  
**ARTG Start Date** 10/11/2018  
**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
Xi' an Friendship Medical Electronics Co Ltd	No9 Gao Xin 1st Road High-Tech Development Zone Xi an, Shaanxi, 710075 China

### Products

#### 1 . Subdermal needle electrode

<b>Product Type</b>	Single Device Product	<b>Effective Date</b>	10/11/2018
<b>GMDN</b>	47714 Subdermal needle electrode		
<b>Intended Purpose</b>	A sterile electrical conductor inserted beneath the dermal layer of a patient's skin to record/monitor electrical activity (biopotentials) for a range of physiological measurements and also to provide electrical stimulation usually for intraoperative monitoring and/or nerve location.		

### Specific Conditions

No Specific Conditions included on Record

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