

Australian Government

Department of Health

Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry: 311381 Symbiotic Devices Pty Ltd - Electrode, electromyograph

ARTG entry for Medical Device Included Class IIa

Sponsor Symbiotic Devices Pty Ltd

Postal Address Suite 138 / 245 Thomas Street, DANDENONG, VIC, 3175

Australia

10/11/2018 ARTG Start Date

Product Category Medical Device Class IIa

Status Active

Medical Devices Approval Area

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

Address Name

No9 Gao Xin 1st Road High-Tech Development

Xi an, Shaanxi, 710075

China

Products

1 . Electrode, electromyograph

Xi' an Friendship Medical Electronics Co Ltd

Product Type Effective Date 10/11/2018 Single Device Product

GMDN 11441 Electrode, electromyograph

Intended Purpose An electrical conductor designed to be inserted into muscle or nerve tissue to detect bioelectrical signals.

Specific Conditions

No Specific Conditions included on Record

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