

Australian Government

Department of Health

Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry: 311382 Symbiotic Devices Pty Ltd - Nerve-locating probe, single-use

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 Ila

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 (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

No9 Gao Xin 1st Road High-Tech Development

Zone

Xi an, Shaanxi, 710075

China

Products

1 . Nerve-locating probe, single-use

Xi' an Friendship Medical Electronics Co Ltd

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

GMDN 61089 Nerve-locating probe, single-use

Intended Purpose A sterile, hand-held surgical instrument intended to function as an electrical conductor to locate a nerve during open surgery, and

for diagnostic purposes (EMG), by delivering controlled electrical impulses to a specific body site for the measurement of a nerve

response.

Specific Conditions

No Specific Conditions included on Record

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