



Australian Government
Department of Health
Therapeutic Goods Administration

Australian Register of Therapeutic Goods Certificate

Issued to

Symbiotic Devices Pty Ltd

for approval to supply

Symbiotic Devices Pty Ltd - Neurophysiologic monitoring system

ARTG Identifier	293809
ARTG Start date	13/09/2017
Product Category	Medical Device Included Class IIa
GMDN	46566
GMDN Term	Neurophysiologic monitoring system
Intended Purpose	Measures and displays the electrical signals generated by peripheral nerves, muscles and the central nervous system. It has a pulse oximeter to detect and display pulse rate and SpO2 levels in the limbs.

Manufacturer Details	Address	Certificate number(s)
Cadwell Industries Inc	909 N Kellogg Street Kennewick, WA, 99336 United States Of America	DV-2017-MC-14741-2

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. Neurophysiologic monitoring system

Product Specific Conditions

.

Therapeutic Goods Administration
PO Box 100, Woden ACT 2606 Australia
Phone: 1800 020 653
Email: info@tga.gov.au

ARTG Identifier: 293809
ARTG Start Date: 13/09/2017