



Australian Government
Department of Health
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry: 291804 Emergo Asia Pacific Pty Ltd T/a Emergo Australia - Dilator, nasal

ARTG entry for Medical Device Included Class 1
Sponsor Emergo Asia Pacific Pty Ltd T/a Emergo Australia
Postal Address Level 20 Tower II Darling Park 201 Sussex Street, SYDNEY, NSW, 2000
Australia
ARTG Start Date 21/07/2017
Product category Medical Device Class 1
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

Provent Sleep Therapy LLC

Address

125 Tolman Avenue
Leominster, MA, 01453
United States Of America

Products

1. Dilator, nasal

Product Type	Single Device Product	Effective date	21/07/2017
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GMDN 11260 Dilator, nasal

Intended purpose Provent Sleep Apnea Therapy is indicated for the treatment of obstructive sleep apnea (OSA).

Specific Conditions

No Specific Conditions included on Record

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