



Australian Government
Department of Health
 Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry: 233172 Emergo Asia Pacific Pty Ltd T/a Emergo Australia - Pillow, <specify>

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 28/01/2015
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	Address
Sleep Specialists LLC	150 Monument Road Suite 207 Bala Cynwyd, PA, 19004 United States Of America

Products

1. Pillow, <specify>

Product Type	Single Device Product	Effective date	28/01/2015
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GMDN 40512 Pillow, <specify>

Intended purpose The device is intended for the treatment of mild to moderate predominately positional obstructive sleep apnea (OSA) and to reduce or alleviate snoring.

Specific Conditions

No Specific Conditions included on Record

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