



Australian Government
Department of Health
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	322573	SLEEP IN HARMONY - Blanket, <specify>
ARTG entry for	Medical Device Included Class 1	
Sponsor	SLEEP IN HARMONY	
Postal Address	PO BOX 244, Gisbourne, VIC, 3437 Australia	
ARTG Start Date	2/09/2019	
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
Chengdu Yixi Textile Co Ltd	No2108 21st Floor Unit 1 Building 8 No1700 North Section of Tianfu Avenue Chengdu High-Tech Zone , China, China

Products

1 . Blanket, <specify>

Product Type	Single Device Product	Effective Date	2/09/2019
GMDN	40488 Blanket, <specify>		
Intended Purpose	The blankets of various sizes and weight, based on consumers individuals needs is to provide comfort, calming, and relaxation. The Blanket's are to assist purchasers with evenly distributed pressure, providing sensory stimulation against the body, creating a calming effect. This is to support those experiencing anxiety, restlessness, unease, irritability, sleeplessness or just for comfort. Due to the weight of the blankets, they should be stored appropriately to avoid tripping or falling over it.		

Specific Conditions

No Specific Conditions included on Record

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