

Australian Government

Department of Health

Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	305742	Compliance Management Solutions - Snoozeal System - Sleep-disordered breathing tongue electrical stimulator	
ARTG entry for	Medical Device Included Class 1		
Sponsor	Compliance Management Solutions		
Postal Address	109 Ridgemont Drive, Berwick, VIC, 3806 Australia		
ARTG Start Date	29/06/2018		
Product category	Medical Device Class 1		
Status	Active		
Approval area	Medical Dev	vices	
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 50 Woodsgate , Leicester, LE3 5GF United Kingdom

Products

1. Snoozeal System - Sleep-disordered breathing tongue electrical stimulator					
Product Type	Medical device system	Effective date	29/06/2018		
GMDN		63489 Sleep-disordered breathing tongue electrical stimulator			
Intended purpose		SnooZeal is intended for the treatment of night-time primary snoring and snoring in mild obstructive sleep apnea patients.			
Specific Conditions					

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