



Australian Government
Department of Health
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	281841	Symbiotic Devices Pty Ltd - Connector, mouthpiece, single-use
ARTG entry for	Medical Device Included Class 1	
Sponsor	Symbiotic Devices Pty Ltd	
Postal Address	Suite 138 / 245 Thomas Street, DANDENONG, VIC, 3175 Australia	
ARTG Start Date	27/10/2016	
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
WR Medical Electronics Co	1700 Gervais Avenue MaplewoodMN 55109 ,, United States Of America

Products

1 . Connector, mouthpiece, single-use

Product Type	Single Device Product	Effective Date	27/10/2016
GMDN	44545 Connector, mouthpiece, single-use		
Intended Purpose	A disposable rigid device that is inserted into the patient's mouth and will provide a gas-tight fitting to the patient's respiratory system through the simple insertion into the mouth and the patient closing his/her lips around it.		

Specific Conditions

No Specific Conditions included on Record

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