



Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	329750	Philips Electronics Australia Ltd - CPAP/BiPAP nasal mask, reusable
ARTG entry for	Medical Device Included (Export Only) Class 1	
Sponsor	Philips Electronics Australia Ltd	
Postal Address	Locked Bag 30, NORTH RYDE BC, NSW, 1670 Australia	
ARTG Start Date	11/02/2020	
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
Respironics Inc	1001 Murry Ridge Lane Murrysville, PA, 15668-8550 United States Of America

Products

1 . CPAP/BiPAP nasal mask, reusable

Product Type	Single Device Product	Effective Date	11/02/2020
GMDN	57815 CPAP/BiPAP nasal mask, reusable		
Intended Purpose	Intended to provide an interface for application of non-invasive ventilation to patients. The mask is for single patient use in the home and multi-patient use in the hospital/institutional environment. The mask is to be used on patients 5 kg/11 lbs or greater for whom non-invasive ventilation has been prescribed.		

Specific Conditions

No Specific Conditions included on Record

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