



Australian Government
Department of Health
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	332300	BYD AUSTRALIA PTY LTD - Public N95 respirator
ARTG entry for	Medical Device Included Class 1	
Sponsor	BYD AUSTRALIA PTY LTD	
Postal Address	Suite 102 Level 1 2 Lyonpark Road, Macquarie Park, NSW, 2113 Australia	
ARTG Start Date	24/03/2020	
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
BYD Precision Manufacture Co Ltd	No 1 Baoping Road Long gang District, Shenzhen, China

Products

1 . Public N95 respirator			
Product Type	Single Device Product	Effective Date	24/03/2020
GMDN	57793 Public respirator, single-use		
Intended Purpose	The KN95 particulate respirator is a respiratory protective device designed to achieve a close facial fit and efficient filtration of airborne particles.		

Specific Conditions
No Specific Conditions included on Record

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