



Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	438510	Detmold Medical Pty Ltd - Surgical/medical respirator, single-use
ARTG entry for	Medical Device Included Class 1	
Sponsor	Detmold Medical Pty Ltd	
Postal Address	PO Box 636, Welland, SA, 5007 Australia	
ARTG Start Date	29/01/2024	
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
Detmold Medical Pty Ltd	45 Chief Street Brompton, SA, 5007 Australia

Products

1 . Surgical/medical respirator, single-use

Product Type	Procedure Pack	Effective Date	29/01/2024
GMDN	57794 Surgical/medical respirator, single-use		
Intended Purpose	The Level 3 N95 Tri-Panel Surgical Respirator is a single use surgical respirator for use in healthcare, where a person is at risk of blood or fluid splash. The mask is designed to filter out non-oil based airborne particles and offers bacterial filtration.		

Specific Conditions

No Specific Conditions included on Record

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