



Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	338435	Ansell Ltd T/A Ansell Healthcare - Polychloroprene examination/treatment glove, non-powdered
ARTG entry for	Medical Device Included Class 1	
Sponsor	Ansell Ltd T/A Ansell Healthcare	
Postal Address	GPO Box 772 H, MELBOURNE, VIC, 3001 Australia	
ARTG Start Date	26/06/2020	
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
Ansell Healthcare Products LLC	2301 Robb Drive Reno, NV, 89523 United States Of America

Products

1 . Polychloroprene examination/treatment glove, non-powdered

Product Type	Single Device Product	Effective Date	26/06/2020
GMDN	56288 Polychloroprene examination/treatment glove, non-powdered		
Intended Purpose	A non-sterile device made of polychloroprene intended as a protective barrier when worn on the hands of healthcare providers during patient examination/treatment or for other sanitary purposes; its inner surface is not covered with talcum powder. The device is used mainly as a two-way barrier to protect both the patient and the staff against various contamination.		

Specific Conditions

No Specific Conditions included on Record

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