



Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry: 407104 Amoena Australia Pty Ltd - Detergent, <specify>

ARTG entry for Medical Device Included Class 1

Sponsor Amoena Australia Pty Ltd

Postal Address PO Box 119, FITZROY, VIC, 3065
Australia

ARTG Start Date 30/03/2023

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
Amoena Medizin Orthopadie Technik Gmbh	36 Kapellenwege Raubling, , 83064 Germany

Products

1 . Detergent, <specify>

Product Type	Procedure Pack	Effective Date	30/03/2023
--------------	----------------	----------------	------------

GMDN 33162 Detergent, <specify>

Intended Purpose The Soft Cleanser gently cleans silicone breast forms, including the contact breast form and silicone pressure pads. Thorough cleansing with the soft cleanser preserves the adhesion of the Contact breast form.
The cleanser removes both skin oil and dead skin cells from the surface.

Specific Conditions

No Specific Conditions included on Record

© Commonwealth of Australia. This work is copyright. You are not permitted to re-transmit, distribute or commercialise the material without obtaining prior written approval from the Commonwealth. Further details can be found at <http://www.tga.gov.au/about/website-copyright.htm>.

Public Summary