



Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry: 362412 Amoena Australia Pty Ltd - Scar management garment, pressure

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 19/04/2021

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 . Scar management garment, pressure

Product Type	Single Device Product	Effective Date	19/04/2021
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GMDN 44954 Scar management garment, pressure

Intended Purpose Scar management compression garments

Specific Conditions

No Specific Conditions included on Record

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