



**Australian Government**  
**Department of Health and Aged Care**  
Therapeutic Goods Administration

## Public Summary

**Summary for ARTG Entry:** 362411 Amoena Australia Pty Ltd - Non-sterile scar management dressing, reusable

**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 . Non-sterile scar management dressing, reusable

<b>Product Type</b>	Single Device Product	<b>Effective Date</b>	19/04/2021
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**GMDN** 44898 Non-sterile scar management dressing, reusable

**Intended Purpose** Non Sterile scar management dressing reusable

### Specific Conditions

No Specific Conditions included on Record

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Public Summary