



Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	406670	Amoena Australia Pty Ltd - Brassiere, surgical
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	23/03/2023	
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 . Brassiere, surgical			
Product Type		Effective Date	
Single Device Product		23/03/2023	
GMDN	10481 Brassiere, surgical		
Intended Purpose	Compression textiles after breast surgery. Surgical brasserie. To prevent the formation of oedema and to support venous return and lymphatic drainage.		

Specific Conditions
No Specific Conditions included on Record

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