



Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	280397	Ebos Group Australia Pty Ltd - DemeCAPRONE Poliglecaprone 25 monofilament synthetic absorbable suture - Suture, poliglecaprone
ARTG entry for	Medical Device Included Class III	
Sponsor	Ebos Group Australia Pty Ltd	
Postal Address	PO Box 100, KINGSGROVE, NSW, 1480 Australia	
ARTG Start Date	16/09/2016	
Product Category	Medical Device Class III	
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
DemeTECH Corp	14175 NW 60th Avenue Miami Lakes, FL, 33014 United States Of America

Products

1 . DemeCAPRONE Poliglecaprone 25 monofilament synthetic absorbable suture - Suture, poliglecaprone

Product Type	Single Device Product	Effective Date	16/09/2016
GMDN	45814 Suture, poliglecaprone		
Functional Description	DemeCAPRONE sutures elicit minimal acute inflammatory reaction in tissues, followed by gradual encapsulation of the suture by fibrous connective tissues. Progressive loss of tensile strength and eventual absorption occurs by means of hydrolysis.		
Intended Purpose	Demecaprone is a synthetic monofilament absorbable suture indicated for use in general soft tissue approximation and/or ligation, but not for use in cardiovascular or neurological surgery, microsurgery or ophthalmic surgery.		
Variant information	Size 6-0 Size 0 Size 1 Size 2-0 Size 3-0 Size 4-0 Size 5-0		

Specific Conditions

No Specific Conditions included on Record

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