



Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry: 158584 Dynek Pty Ltd - Vilene - Suture, polyvinylidene fluoride

ARTG entry for Medical Device Included Class III

Sponsor Dynek Pty Ltd

Postal Address PO Box 2346, PORT ADELAIDE, SA, 5015
Australia

ARTG Start Date 19/01/2009

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
Dynek Pty Ltd	9 Circuit Drive HENDON, SA, 5014 Australia

Products

1 . Vilene - Suture, polyvinylidene fluoride

Product Type	Single Device Product	Effective Date	19/01/2009
GMDN	38873 Suture, polyvinylidene fluoride		
Functional Description	Suture, non-absorbable, synthetic, monofilament, blue, with surgeon able to choose appropriate thread diameter and length according to surgical requirement		
Intended Purpose	Surgical procedures for tying off, ligation and/or tissue approximation		
Variant information	Length (cm) 10 - 250 Diameter (mm) 0.001 - 0.999		

Specific Conditions

No Specific Conditions included on Record

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