



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

## Public Summary

**Summary for ARTG Entry:** 158583 Dynek Pty Ltd - Biovek - Suture, polyglycolic acid

**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 . Biovek - Suture, polyglycolic acid

<b>Product Type</b>	Single Device Product	<b>Effective Date</b>	19/01/2009
<b>GMDN</b>	13908 Suture, polyglycolic acid		
<b>Functional Description</b>	Suture, absorbable, synthetic, braided multifilament, absorption by hydrolysis providing consistent absorption irrespective of patient health		
<b>Intended Purpose</b>	Surgical procedures for tying off, ligation and/or tissue approximation		
<b>Variant information</b>	Length (cm) 10 - 250 Diameter (mm) 0.001 - 0.799 Suture, colour Violet or undyed (clear)		

### Specific Conditions

No Specific Conditions included on Record

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