



**Australian Government**  
**Department of Health**  
**Therapeutic Goods Administration**

<b>Record Summary</b>	360056	Precise Medical Supplies Pty Ltd - Hypodermic needle, single-use, sterile
<b>Sponsor</b>	Precise Medical Supplies Pty Ltd	
<b>Therapeutic Type</b>	Medical Device	
<b>Product Category</b>	Included Class IIa	
<b>ARTG Start Date</b>	7/04/2021	
<b>Postal Address</b>	PO Box 421, Paddington, NSW, 2021 Australia	
<b>Billing Address</b>	PO Box 421, Paddington, NSW, 2021 Australia	
<b>Product Type</b>	Medical Device - Class IIa - Included	
<b>Status</b>	Active	
<b>Approval Area</b>	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	Certificate number(s)
ASTI CORPORATIONS	2804 Yonezu-cho Minami-ku Hamamatsu Hamamatsu , Shizuoka , 432-8056 Japan	DV-2021-MC-06057-1

#### Products

##### 1 . Hypodermic needle, single-use, sterile

<b>Product Type</b>	Single Device Product	<b>Status</b>	Current
		<b>Effective Date</b>	7/04/2021
<b>GMDN</b>	59230 Hypodermic needle, single-use, sterile		
<b>Functional Description</b>	Not included on record		
<b>Intended Purpose</b>	Single-use sterile needle intended to be used for medical purposes to inject fluids into intradermal tissue, subcutaneous tissue or muscle tissue.		

#### Variant Information

##### Device Information

10 Single-use devices

##### Specific Conditions

No Specific Conditions included on Record

Record Summary