



Australian Government
Department of Health
Therapeutic Goods Administration

Record Summary	375973	WESTLAB PTY LTD - Needle, blood collecting
Sponsor	WESTLAB PTY LTD	
Therapeutic Type	Medical Device	
Product Category	Included Class IIa	
ARTG Start Date	8/10/2021	
Postal Address	PO Box 1680, Ballarat, VIC, 3354 Australia	
Billing Address	PO Box 1680, Ballarat, VIC, 3354 Australia	
Product Type	Medical Device - Class IIa - Included	
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	Certificate number(s)
Disera Tibbi Malzeme Lojistik Sanayi ve Ticaret Anonim Sirketi	Ibni Melek OSB Mah Tosbi Yol 5 Sokak No 46 Tire , Izmir , Turkey	DV-2021-MC-17319-1

Products

1 . Needle, blood collecting

Product Type	Single Device Product	Status	Current
		Effective Date	8/10/2021
GMDN	35209 Needle, blood collecting		
Functional Description	Not included on record		
Intended Purpose	Intended to be used for blood collection.		

Variant Information

Device Information

- 10 Single-use devices
- 06 In vitro diagnostic devices

Specific Conditions

No Specific Conditions included on Record

Record Summary