



Australian Government
Department of Health
Therapeutic Goods Administration

Record Summary	376030 WESTLAB PTY LTD - Specimen receptacle IVDs
Sponsor	WESTLAB PTY LTD
Therapeutic Type	Medical Device
Product Category	Included - IVD Class 1
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 1 - Included - IVD
Status	Active
Approval Area	IVD

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	

Products

1 . Specimen receptacle IVDs

Product Type	IVD	Status	Current
This entry:	does not contain System(s)/Procedure Pack	Effective Date	8/10/2021
GMDN	CT936 Specimen receptacle IVDs		
Functional Description	Not included on record		
Intended Purpose	Intended to be used to collect, transport and process blood for testing serum, plasma or whole blood.		

Variant Information

Device Information

06 In vitro diagnostic devices

Specific Conditions

No Specific Conditions included on Record

Record Summary