



Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	405284	Abacus dx Pty Ltd - Clinical chemistry biological screening IVDs
ARTG entry for	Medical Device Included - IVD Class 2	
Sponsor	Abacus dx Pty Ltd	
Postal Address	PO Box 446, WATERFORD, QLD, 4133 Australia	
ARTG Start Date	22/02/2023	
Product Category	Medical Device Class 2	
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
LGC Clinical Diagnostics Inc	221 US Route 1 Cumberland Foreside, ME, 04110-1345 United States Of America

Products

1 . Clinical chemistry biological screening IVDs

Product Type	IVD	Effective Date	22/02/2023
GMDN	CT1236 Clinical chemistry biological screening IVDs		
Intended Purpose	VALIDATE Urine Chemistry kits are designed to assist in the documentation of linearity, calibration verification, and verification of linear range or provide assistance when troubleshooting instrument systems, reagent problems, and calibration anomalies.		

Specific Conditions

No Specific Conditions included on Record

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