



Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry: 399244 Abacus dx Pty Ltd - Clinical chemistry therapeutic drug monitoring 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 11/11/2022

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 therapeutic drug monitoring IVDs

Product Type	IVD	Effective Date	11/11/2022
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GMDN CT860 Clinical chemistry therapeutic drug monitoring IVDs

Intended Purpose Therapeutic drug monitoring calibration verification and/or linearity test kits

Specific Conditions

No Specific Conditions included on Record

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