



**Australian Government**  
**Department of Health and Aged Care**  
Therapeutic Goods Administration

## Public Summary

**Summary for ARTG Entry:** 407518 Abacus dx Pty Ltd - Clinical chemistry vitamin and mineral 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** 12/04/2023

**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
Quantimetrix Corporation	2005 Manhattan Beach Boulevard Redondo Beach, CA, 90278 United States Of America

### Products

#### 1 . Clinical chemistry vitamin and mineral IVDs

Product Type	IVD	Effective Date	12/04/2023
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**GMDN** CT847 Clinical chemistry vitamin and mineral IVDs

**Intended Purpose** Controls intended to monitor the performance of clinical assays used to quantitate vitamins and minerals including total 25-OH Vitamin D.

### Specific Conditions

No Specific Conditions included on Record

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