



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

## Public Summary

<b>Summary for ARTG Entry:</b>	396882	Abacus dx Pty Ltd - Clinical chemistry substrate IVDs
<b>ARTG entry for</b>	Medical Device Included - IVD Class 2	
<b>Sponsor</b>	Abacus dx Pty Ltd	
<b>Postal Address</b>	PO Box 446, WATERFORD, QLD, 4133 Australia	
<b>ARTG Start Date</b>	4/10/2022	
<b>Product Category</b>	Medical Device Class 2	
<b>Status</b>	Active	
<b>Approval Area</b>	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
Aidian Oy	Koivu-Mankkaan tie 6 B PO Box 83 Espoo, Finland, FI-02101 Finland

### Products

#### 1 . Clinical chemistry substrate IVDs

Product Type	IVD	Effective Date	4/10/2022
<b>GMDN</b>	CT833 Clinical chemistry substrate IVDs		
<b>Intended Purpose</b>	IVDs used on the QuikRead go instrument for the qualitative and/or quantitative determination of clinical chemistry substrates in a clinical specimen, including HbA1c for monitoring long term control of glucose from diabetes mellitus or as an aid in diagnosing diabetes. These assays and controls are intended to be used by trained healthcare professionals in clinical laboratories and/or near-patient/point-of-care testing settings.		

### Specific Conditions

No Specific Conditions included on Record

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