



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

## Public Summary

<b>Summary for ARTG Entry:</b>	422690	Abacus dx Pty Ltd - Plasmodium (malaria) IVDs
<b>ARTG entry for</b>	Medical Device Included - IVD Class 3	
<b>Sponsor</b>	Abacus dx Pty Ltd	
<b>Postal Address</b>	PO Box 446, WATERFORD, QLD, 4133 Australia	
<b>ARTG Start Date</b>	27/09/2023	
<b>Product Category</b>	Medical Device Class 3	
<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
SD Biosensor Inc	C-4th & 5th 16 Deogyong-daero 1556beon-gil Yeongtong-gu Suwon-si, Gyeonggi-do, 16690 Korea - Republic of

### Products

#### 1 . Plasmodium (malaria) IVDs

<b>Product Type</b>	IVD	<b>Effective Date</b>	27/09/2023
<b>GMDN</b>	CT816 Plasmodium (malaria) IVDs		
<b>Intended Purpose</b>	STANDARD Q Malaria Tests are a rapid and membrane based immunochromatography for qualitative detection of malaria in human capillary and venous whole blood specimens. This product is not intended for self-testing.		

### Specific Conditions

No Specific Conditions included on Record

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Public Summary