



Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	213355	Atomo Diagnostics Limited - Infectious disease IVDs
ARTG entry for	Medical Device Included - IVD (Export Only) Class 1	
Sponsor	Atomo Diagnostics Limited	
Postal Address	Level 1 3-5 George Street, Leichhardt, NSW, 2040 Australia	
ARTG Start Date	20/08/2013	
Product Category	Medical Device Class 1	
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
Atomo Diagnostics Limited	Level 1 3-5 George Street Leichhardt, NSW, 2040 Australia

Products

1 . Infectious disease IVDs			
Product Type	IVD	Effective Date	31/08/2018 9:24:41 AM
GMDN	CT701 Infectious disease IVDs		
Intended Purpose	Infectious Disease IVDs - For Export Only		

Specific Conditions

No Specific Conditions included on Record

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