



Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry: 274314 APAC Security Pty Ltd - Clinical chemistry toxicology/drug detection IVDs

ARTG entry for Medical Device Included - IVD Class 2
Sponsor APAC Security Pty Ltd
Postal Address Unit C8A / 15 Narabang Way, Belrose, NSW, 2085
Australia
ARTG Start Date 14/04/2016
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
Hangzhou Clongene Biotech Co Ltd	Buiding 4 No 20 Longquan Road Cangqian Town Yuhang District, Hangzhou, 311121 China

Products

1 . Clinical chemistry toxicology/drug detection IVDs

Product Type	IVD	Effective Date	14/04/2016
GMDN	CT184 Clinical chemistry toxicology/drug detection IVDs		
Intended Purpose	On Site Drug of abuse screening device		

Specific Conditions

No Specific Conditions included on Record

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