



Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry: 343135 Emergence Technology Pty Ltd - Specimen receptacle IVDs

ARTG entry for Medical Device Included - IVD Class 1

Sponsor Emergence Technology Pty Ltd

Postal Address PO Box 420, Brunswick, VIC, 3056
Australia

ARTG Start Date 8/09/2020

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
Ustar Biotechnologies (Hangzhou) Ltd	Room 801-808 3766 Nanhuan Road Fl 8 Binjiang Dist Hangzhou, Zhejiang, 310053 China

Products

1 . Specimen receptacle IVDs

Product Type	IVD	Effective Date	8/09/2020
GMDN	CT936 Specimen receptacle IVDs		
Intended Purpose	Vessels with or without additives that are intended to be used for the collection, containment, preservation and/or transport of clinical specimens for analysis or investigation.		

Specific Conditions

No Specific Conditions included on Record

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