



Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	346952	Emergence Technology Pty Ltd - Instrument/analyser 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	2/11/2020	
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 . Instrument/analyser IVDs			
Product Type	IVD	Effective Date	2/11/2020
GMDN	CT943 Instrument/analyser IVDs		
Intended Purpose	This product is a semi-automated nucleic acid amplification and detection analyser - it is based on a three-stage magnetically permeable extraction technology and the principle of fluorescence polymerase chain reaction, and is used together with a matching detection kit for qualitative detection of pathogen nucleic acid sequences from a clinical specimen.		

Specific Conditions
No Specific Conditions included on Record

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