



Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	434210	Equinox Medical Pty Ltd - Instrument/analyser IVDs
ARTG entry for	Medical Device Included - IVD Class 1	
Sponsor	Equinox Medical Pty Ltd	
Postal Address	Sydney Knowledge Hub Level 2 Merewether Building H04, University of Sydney, Camperdown, NSW, 2006 Australia	
ARTG Start Date	16/01/2024	
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
Guangzhou Four E's Healthcare Co Ltd	Room 405 Building C No 2 Ruitai Road Huangpu District Guangzhou, Guangdong, China

Products

1 . Instrument/analyser IVDs

Product Type	IVD	Effective Date	16/01/2024
GMDN	CT943 Instrument/analyser IVDs		
Intended Purpose	The Real-Time Fluorescent Quantitative PCR System uses fluorescence real-time detection method to analyze the amplification of PCR template. It is suitable for use as an in vitro diagnostic medical device (IVD) for the purposes of processing, examining and/or providing information about a clinical specimen.		

Specific Conditions

No Specific Conditions included on Record

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