



Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry: 430255 Equinox Medical Pty Ltd - General laboratory reagent and consumables IVDs

ARTG entry for Medical Device Included - IVD Class 2

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 7/12/2023

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
BEAVER Biomedical Engineering Co Ltd	NE36 Nanopolis Suzhou 99 Jinji Lake Avenue , Suzhou Industrial Park, China

Products

1 . General laboratory reagent and consumables IVDs

Product Type	IVD	Effective Date	7/12/2023
--------------	-----	----------------	-----------

GMDN CT946 General laboratory reagent and consumables IVDs

Intended Purpose This product is intended for the isolation and purification of nucleic acids from human samples. It is designed for use in diagnostic applications and procedures. This product should only be used by trained professionals.

Specific Conditions

No Specific Conditions included on Record

© Commonwealth of Australia. This work is copyright. You are not permitted to re-transmit, distribute or commercialise the material without obtaining prior written approval from the Commonwealth. Further details can be found at <http://www.tga.gov.au/about/website-copyright.htm>.

Public Summary