



Australian Register of Therapeutic Goods Certificate

Issued to

Hough Pharma Pty Ltd

for approval to supply

Instrument/analyser IVDs

ARTG Identifier 372750
ARTG Start Date 12/08/2021
Product Category Medical Device Included - IVD Class 1
GMDN CT943
GMDN Term Instrument/analyser IVDs
Intended Purpose This product is intended for the fluorescence immunoassay and analysis of dedicated fluorescence testing card.

Manufacturer Details	Address	Certificate number(s)
BIOHIT HealthCare (Hefei) Co Ltd	Building D9 Floor 1-4 Innovation Park West Wangjiang Road No 800 High-Tech Zones Hefei , Anhui , 23008 8 China	

ARTG Standard Conditions

The above Medical Device Included - IVD Class 1 has been entered on the Register subject to the following 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.

Products Covered by This Entry

1. Instrument/analyser IVDs

This entry: does not contain System(s)/Procedure Pack(s)

IVD Information

Name	Category Description
Fluorescent Immunoassay Analyzer	Point of care testing

Product Specific Conditions

No specific conditions have been recorded against this entry.