MANUFACTURER'S DECLARATION OF CONFORMITY

AUSTRALIAN THERAPEUTIC GOODS (MEDICAL DEVICES) REGULATIONS 2002
Full Quality Assurance Procedures

This is a declaration made in accordance with the requirements of Clause 1.8 of Schedule 3 of the Australian Therapeutic Goods (Medical Devices) Regulations 2002 relating to In Vitro Diagnostic Medical Devices.

Reference:	*New Coronavirus (SARS-CoV-2) N Protein Detection Kit (Fluorescence Immunochromatography)*
Manufacturer's Name:	*Beijing Savant Biotechnology Co., Ltd.*
Business Address:	*14# 4F* *No. 2 Kechuang East 5th Street,* *Tongzhou District* *101111 Beijing* *PEOPLE'S REPUBLIC OF CHINA*
IVD Medical Device(s):	*New Coronavirus (SARS-CoV-2) N Protein Detection Kit (Fluorescence Immunochromatography)*
Classification:	*Class 3 IVD*
GMDN Code and Term:	*Severe acute respiratory syndrome-associated coronavirus IVDs (CT772)*
Scope of Application:	*All batches.*

Each kind of IVD medical device to which the Full Quality Assurance Procedures have been applied complies with the applicable classification rules and essential principles, at each stage from the design of the device until its final inspection before being supplied.

This declaration is being made on the basis of the following certificates:

Full Quality Management System Certificate:

EN ISO 13485:2016 (Certificate Number: Q5 095022 0002 Rev. 01)
TUV SUD Product Service GmbH, Ridlerstraße 65, 80339 Munich, Germany

Design Examination Certificate:

n/a

Conformity Assessment Standards Applied:

n/a

Authorised Signatory:

Name, Position

2020.5.8

Date