DoChek 德成生物

MANUFACTURER'S DECLARATION OF CONFORMITY

AUSTRALIAN THERAPEUTIC GOODS (MEDICAL DEVICES) REGULATIONS 2002

VERIFICATION PROCEDURES

This is a declaration of conformity made under clause 1.8 of Schedule 3 to the Therapeutic Goods (Medical Devices) Regulations 2002.

Manufacturer's name:	Guangzhou Decheng Biotechnology Co., LTD,
Business address:	Room 218, Building 2, No.68, Nanxiang Road, Science City, Huangpu District, 510663, Guangzhou P.R. China
Medical device(s):	V-Chek 2019-nCoV Ag Saliva Rapid Test Card (Immunochromatography). Test card x1- 0589C 4X001 Test card x5 - 0589C 4X005 Test card x10 - 0589C 4X010 Test card x15 - 0589C 4X015 Test card x 20 - 0589C 4X020
Classification:	Class 3 IVDs
GMDN code and term:	64912, SARS-CoV-1/SARS-CoV-2 antigen IVD, kit, immunochromatographic test (ICT), rapid
Scope of application:	All batches

Each kind of medical device to which the system has been applied complies with the applicable provisions of the essential principles, the classification rules, and the full quality assurance procedures, at each stage, from the design of the device until its final inspection before being supplied.

Full quality assurance procedures certificate:	Certificate CN21/42239 SGS ISO 13485:2016 and EN ISO 13485:2016 valid 16th March 2021 15th March 2024		
Design examination certificate (if applicable):	NA		
Standards applied:	EU Declaration of conformity according to the in vitro Diagnostic Medical Device Directive 98/79/EC		
	EN ISO 18113-1:2011	EN ISO 23640:2015	EN 13641:2002
	EN ISO 15223-1:2016	EN ISO 13485:2016	EN 62366:2008
	EN ISO 14971:2019	EN ISO 18113-2:2011	EN 13612:2002

Authorised signatory:

<signed by the person authorised by the manufacturer>

GUANGZHOU DECHENG BIOTECHNOLOGY CO., LTD DoChek

Signature

Name, Position Sales Director

Date 25th Aug 2021