# EU DECLARATION OF CONFORMITY

According to the in vitro Diagnostic Medical Device Directive 98/79/EC
Doc No.:DC-DOC-0685C01

| | |
|---|---|
| **Manufacturer:** | Guangzhou Decheng Biotechnology Co.,LTD |
| **Address:** | Room 218 and Room 212, Building 2, No. 68, Nanxiang 1st Road, Science City, Huangpu District, Guangzhou, Guangdong, 510663, P.R. China |
| **European Representative:** | Caretechion GmbH<br>Niederrheinstr. 71, 40474 Duesseldorf, Germany |
| **Product Name:** | 2019-nCoV Ag Rapid Test Kit (Immunochromatography) |
| **Cat. No.:** | 0685C2X001 0685C2X005 0685C2X025 |
| **IVDD Classification:** | Non-Annex II, for self-testing |
| **Applied Common Specifications/ Standards:** | EN ISO 18113-1:2011 EN ISO 18113-4:2011<br>EN ISO 15223-1:2016 EN 13641:2002<br>EN ISO 14971:2019 IEC 62366-1:2015<br>EN ISO 23640:2015 EN 13612:2002<br>EN 13532:2002 EN ISO 13485:2016 |
| **Conformity assessment procedure:** | Annex III, including 6 |
| **Notified Body:** | EC Certificate number IVDD 21 041 0104 has been issued by the Notified Body:<br>bqs. s.r.o.\| NB 2854 \| SKTC -180 \|<br>Studentska 12, Trencin<br>Slovakia |
| **Valid from:** | 22 October 2021 |
| **Valid until:** | 26 May 2022 |

Technical documentation demonstrating compliance
is kept by the manufacturer and can be made available by the authorized representative in Europe.

This declaration of conformity is issued under the sole responsibility of the manufacturer that the above product(s) meet(s) the provisions of the European Directive 98/79/EC for in vitro Diagnostic Medical Devices and comply with the above applied standards.

**Signature:** 刘伟平

**Position:General Manager**

**Place:Guangzhou**

**Date:** October 22, 2021