Declaration of Conformity

Manufacturer:	Nantong Diagnos Biotechnology Co.,Ltd. Room 203, Building 6, Electronic Information Industrial Park, No. 2 Haiyang South Road, Chengnan Street, Rugao City, Jiangsu Province, PEOPLE'S REPUBLIC OF CHINA.
whose single Authorized **EU**-*Representative:* :	CMC MEDICAL DEVICES & DRUGS S.L. C/ Horacio Lengo No 18, CP 29006, Málaga, Spain Tel: +34 951 214 054 E-mail: info@cmcmedicaldevices.com
Product Name:	COVID-19 Antigen Saliva Test kit (Colloidal Gold)

Classification : **Others of ANNEX II of IVDD**

Conformity Assessment Route: **Annex III**

We herewith declare that the above mentioned products meet the transposition into national law, the provisions of the following EC Council Directives and Standards. All supporting documentations are retained under the premises of the manufacturer.

General applicable directives:

In Vitro Diagnostic Medical Devices DIRECTIVE 98/79/EC

Harmonized standards:

EN ISO 13485:2016	EN ISO 15223-1：2016
EN 13612:2002	EN 13641:2002
EN 13975: 2003	EN ISO 14971:2012
EN ISO 18113-1:2011	EN ISO 18113-2:2011
EN ISO 23640:2015	EN ISO 17511: 2003
EN 62366：2008	

Signature:	Tang Shi Jun
Name:	Tang Shi Jun
Title:	General Manager
Place, Date of Issue:	Nantong, 2020-11-05

NANTONG DIAGNOS BIOTECHNOLOGY CO.,LTD. 南通戴尔诺斯生物技术有限公司