NH 纳达康
Nano Diagnosis for Health

CE

DECLARATION OF CONFORMITY

Manufacturer	**Name:** Wuhan NanoDiagnosis for Health Biotechnology Co., Ltd. **Address:** Fl.1-5, Building B4,Biolake,666 Gaoxin Avenue,Donghu New Technology Development Zone, Wuhan City, Hubei Province, 430075, P.R.China
European Representative	**Name:** Lotus NL B.V. **Address:** Koningin Julianaplein 10, 1e Verd, 2595AA, The Hague, Netherlands

The EC declaration of conformity is issued under the sole responsibility of the manufacturer.

Product Name: SARS-CoV-2 Neutralizing Antibody Rapid Test Cassette(Colloidal Gold Method)

Type/Mode: 1/5/10/20/30 Tests/Kit

Product short description and intended use: This kit applies the blocking assay technology to test SARS-CoV-2 neutralizing antibody in human whole blood , serum or plasma specimens. Using purified receptor binding domain (RBD), protein from the viral spike (S) protein and the host cell receptor ACE2, this kit is designed to mimic the virus-host interaction by direct protein-protein interaction on the test strip. If there is SARS-CoV-2 neutralizing antibody to in the specimen and their concentration exceed the limit of detection, the antibody will bind to RBD marker and block RBD binding to the ACE2 in the test area (T line), not showing a red reaction line, it indicate a positive in neutralizing antibody; otherwise, it is negative. The quality control area (C line) should be colored to indicate that the test is valid.

Classification: IVD Device other than the ones listed in Annex II-IVDD 98/79/EEC as List A , List B and Self-testing.

EDMA CODE: 15 04 40 19

Conformity assessment route: IVDD 98/79/EC Annex III.

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The device that is covered by the present declaration bears the mark:

We herewith declare that the above mentioned product meet the provisions of the council directive 98/79/EC. All supporting documents are retained under the premises of the manufacture.

Standards applied:

EN ISO 18113-1:2011	EN ISO 18113-2:2011	
EN ISO 18113-3:2011	EN 13612:2002	EN ISO 14971:2012
EN 62366:2008	EN ISO 13485:2016	EN ISO 15223-1:2016
EN23640:2015	EN 13641:2002	

Place, Date of issue: Wuhan, Hubei, Jan25, 2021

Signature of General Director: Jin Wei