

Statement:

According Directive 98/79/EC on *In Vitro Diagnostic Medical Devices*, Annex III. This declaration of conformity is issued under the sole responsibility of Suny (Xiamen) Biotechnology Co., Ltd.

Manufacturer Information:

Manufacturer Name: Suny (Xiamen) Biotechnology Co., Ltd.
Postal Address: Floor 3 to 8, Building 24, No. 71 Houxiang Road, Haicang District,
Postcode: 361026
City & Country: Xiamen, Fujian, P.R. China.
Telephone Number: +86 0592 6312 399
Web-site: www.sunybio.cn

European Representative:

ECRP Name: Lotus NL B.V.
Postal Address: Koningin Julianaplein 10,1e Verd, 2595AA, The Hague, Netherlands.
Postcode: 2595AA
City & Country: Netherlands.
Telephone Number: +31 64 41 68 999
E-Mail Address: peter@lotusnl.com

In Vitro Diagnostic Directive:

Product Name: Rapid SARS-CoV-2 & FluA & FluB Antigen Test (Colloidal Gold)
Model: S6061701, S6061702, S6061703, S6061704, S6061705
Packing Specification: 1 Test/ Kit, 5 Tests/ Kit, 10 Tests/ Kit, 20 Tests/ Kit, Other specifications
GMDN Code: 65454
Category: For Self-Test
Conformity assessment route: Declaration of Conformity 98/79/EC Annex III section 6

Statement of Responsibility:

We, Suny (Xiamen) Biotechnology Co., Ltd. here with declare with sole responsibility that our product/s mentioned above meet/s the provisions of the Directive 98/79/EC of the European Parliament and of the Council on *In Vitro Diagnostic Medical Devices*. We agree to develop, implement and maintain a documented post-production monitoring process.

Supplementary Information (If Applicable):

We hereby declare that the product described above, to which this declaration of conformity refers to, is in conformity with the essential requirements of the following international standards:

EN ISO 13485:2016;	EN ISO 18113-1:2011;	EN 13612:2002;	EN ISO 15223-1:2016;
EN ISO 14971:2019;	EN ISO 18113-2:2011;	EN 13641:2002;	EN ISO 23640:2015;
EN 62366-1:2015;	EN ISO 18113-3:2011;	EN 13532:2002;	

Signature and Stamp:


General Manager

For and on Behalf of M/s. Suny (Xiamen) Biotechnology Co., Ltd.

Place: Xiamen, China.

Date : 2022.04.15