

## Declaration of Conformity

Manufacture:

Jiangsu Well Biotech Co. Ltd.

No. 9 Changyang Rd.

Changzhou, Jiangsu Province, P.R. China

European Representative:

Lotus NL B.V.Koningin Julianaplein 10, 1e Verd,

2595AA, The Hague, Netherlands

**Product Name:** 

**COVID-19 Ag Rapid Saliva Test Device** 

Cat# CO-03

Classification:

Others not covered by Annex II and self-testing

according to Directive 98/79/EC

We here with declare that the above mentioned products meet the provision of The Council Directive 98/79/EC under our sole responsibility.

Conformity assessment was performed according to Annex III. The following harmonized standard was used to ensure the product conformity with essential requirement Directive 98/79/EC.

EN ISO 13485:2016

EN ISO 14971:2012

EN ISO 15223-1:2016

EN 13641:2002

CE

Name:

Xiulan.Zhang

Position:

Management Representative

Signature:

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Date:

12/24/2020