

## 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 IgM/IgG Rapid Test (Colloidal Gold)**

Classification: IVDD Others

Conformity Assessment Route: Annex III

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



Name: Xiulan.Zhang

Position: Management Representative

Signature: 张秀兰

Date: 06/06/2020