

Declaration of Conformity

Manufacture: **Biotech Co. Ltd.**
No.45 Chang Rd.
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: Wendy.Zing

Position: Management Representative

Signature: 

Date: 06/06/2020