Declaration of Conformity

Manufacturer:
Name: Shenzhen Lifotronic Technology Co., Ltd.
Address: Unit A, 4th Floor, Building 15, Yijing Estate, No.1008 Songbai Road, Nanshan District, Shenzhen City, Guangdong Province, 518055, P.R.China

European Representative:
Name: Shanghai International Holding Corp. GmbH (Europe)
Address: Eiffestrasse 80, 20537 Hamburg，Germany
Tel: +49-40-2513175 Fax: +49-40-255726

Product Name:
SARS-CoV-2 Neutralization Ab(Lateral Flow Immunoassay)（25Tests/Kit）

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

Conformity Assessment Route:
We herewith declare that the above mentioned products and its accessories meet the following EC Council Directive and standards. All supporting documentation is retained under the premises of the manufacturer.

General Applicable Directives:
Medical Device Directive: DIRECTIVE 98/79/EEC of the European Parliament and of the council of 27 October 1998 on in vitro diagnostic medical devices.

Standards Applied of IVD Reagent:

EN 13640:2002	EN ISO 14971: 2012	EN ISO 18113-1:2011
EN 13612:2002	EN ISO 15223-1:2016	EN ISO 18113-2:2011
EN 13641:2002	EN ISO 13485: 2016	EN ISO 17511:2003

Signature: 

Name : Xiang Lei
Position: Director
Place, Date of Issue: Shenzhen, Dec 4, 2020

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