CE

Declaration of Conformity

Manufacturer: Hangzhou Lysun Biotechnology Co., Ltd.
Address: 6th Floor, 6th Building, No.95 Binwen Road, Xixing Street, Binjiang District, Hangzhou, Zhejiang, China

European Representative: Lotus NL B.V.
Koningin Julianaplein 10, 1e Verd, 2595AA, The Hague, Netherlands

Products:
COVID-19 antigen Rapid Test Device(Colloidal Gold)

Classification: Other IVD Devices
Model code: COV-201
Conformity assessment route: Declaration of Conformity IVDD Annex III（except III.6）

We herewith declare that the above mentioned products meet the provisions of the following EC Council Directives and Standards. With sole repponsibility all supporting documentations are retained under the premises of the manufacturer.

DIRECTIVES

General applicable directives:
Medical device directive: Council Directive 98/79/EC concerning in vitro diagnostic medical devices (IVDD 98/79/EC).
Standards Applied:

EN ISO 13485:2016
EN ISO 14971:2012
EN ISO 18113-1:2011
EN ISO 18113-2:2011
EN 13975:2003
EN 17511:2003
EN ISO 15223-1:2016
EN 13612:2002/AC:2002
EN ISO 23640:2015
EN 62366:2008

Place, date of issue: Hangzhou Zhejiang P.R. China 2020/08/04
Signature of General Manager:

Seal/Stamp:

Hangzhou Lysun Biotechnology Co., Ltd.