

Declaration of Conformity

Manufacturer:

Jiangsu Superbio Biomedical (Nanjing) Co., Ltd.
Address: Room 507-511, Block A, Sino-Danish
Ecological Life Science Industrial Park, No.3-1
Xinjihu Road, Jiangbei New Area, Nanjing, China

Whose single Authorized EU-Representative:

Luxus Lebenswelt GmbH
Kochstr.1, 47877, Willich, Germany
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Contactor: Lin Sun
Tel: 0049- 1715605732
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Product Name: SARS-CoV-2 (COVID-19) IgM/IgG Antibody Fast Detection Kit (Colloidal Gold)

Classification: Others of ANNEX II of IVDD
Conformity Assessment Route: Annex III

We herewith declare that the above mentioned products meet the transposition into national law, the provisions of the following EC Council Directives and Standards. All supporting documentations are retained under the premises of the manufacturer.

General applicable directives:

In Vitro Diagnostic Medical Devices DIRECTIVE 98/79/EC

Harmonized standards:

EN ISO 13485:2016, EN ISO 15223-1:2016, EN ISO 14971:2012, EN 13641: 2002,
EN ISO 18113-1:2011, EN ISO 18113-2:2011, EN 13612: 2002, EN ISO 23640:2015

Signature: gingkun wang

Name:

Title:

Position:

General manager

Nanjing

Issue Date: 2020-03-09

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CE