

LABNOVATION TECHNOLOGIES, INC.

DECLARATION OF CONFORMITY

Manufacturer:

Labnovation Technologies, Inc.

Address: 101 and 5th Floor, Building 1, No. 68,18th Road, Guangming Hi-Tech Park, Tangjia Community, Fenghuang Street, Guangming District, Shenzhen 518107, Guangdong, China

EC Representative:

MedNet GmbH
Borkstrasse 10 48163
Muenster, Germany

Product Name:

COVID-19 (SARS-CoV-2) IgM/IgG Antibody Test Kit (Immunochromatography Assay)

Classification: Others of ANNEX II of IVDD

Conformity Assessment Route: Annex III

The manufacturer declares that the above-mentioned products meet the transposition into national law, the provisions of the following EC directives and standards. All supporting documents are remained under the premises of the manufacturer.

General Applicable Directives: 98/79/EC

Standards: EN ISO 13485: 2016, EN ISO 15223-1: 2016, EN ISO 14971: 2012, EN 13975: 2003, EN ISO 18113-1: 2011, EN ISO 18113-2: 2011, EN 13612: 2002, EN ISO 17511: 2003, EN ISO 23640: 2015, EN 13641: 2002, EN 13975: 2003, EN 62366: 2008



Signature:

Name:

Title:

Place:

Date:



Hu Yajun

Managing Director

Shenzhen, China

March 2, 2020