EC Declaration of Conformity

In accordance with Directive 98/79/EC

CE

Manufacturer:

Hangzhou Laihe Biotech Co.,Ltd,located at 1st Floor, Room 505 - 512, 5th Floor, No.2B Building, No.688, Bin' an Road, Changhe Sub-district, Binjiang District, Hangzhou, Zhejiang, China

Declares, that the products

Product Name and Model(s):

Novel Coronavirus (2019-nCoV) IgG Antibody Test Kit (Colloidal Gold),303005

Novel Coronavirus (2019-nCoV) IgM Antibody Test Kit (Colloidal Gold),303004

Novel Coronavirus (2019-nCoV) IgM/IgG Antibody Combo Test Kit (Colloidal Gold),303002

Classification Under IVDD: Others

Conformity assessment route: 98/79/EC Annex III (EC DECLARATION OF CONFORMITY)

We, the Manufacturer, herewith declare with sole responsibility that our products mentioned above meet the provisions of the Directive 98/79/EC of the European Parliament and of the Council on In-Vitro Diagnostic Medical Devices.

We hereby explicitly appoint

EC Representative's Name: Ferro Pharma Europe Ltd.

EC Representative's Address: Ta Maggi Ind. Park, Administration Building – Level 2, Triq San Leonardu, Xghajra, XJR 2306, Malta.

Standards Applied:

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

I, the undersigned,hereby declare that the medical devices specified above conform with the directive 98/79/EC on in vitro diagnostic medical devices and pertinent essential requirements

Date Signed: Mar 18, 2020

杭州莱和生物技术有限公司

Name of authorized signatory: Ou Yangyun

Position held in the company: General manager