EC DECLARATION OF CONFORMITY

According to Directive 98/79/EC on *in vitro* diagnostic medical devices, Annex III

Manufacturer:	Shanghai Kehua Bio-engineering Co., Ltd. 1189 North Qinzhou Road, 200233, Shanghai P.R.China
EC- Representative:	DIAneering® Diagnostics Engineering & Research GmbH Friedrichstrasse 26, D-69221 Heidelberg-Dshm, Germany
Product:	Diagnostic Kit for SARS-CoV-2 IgM/IgG Antibody (Colloidal Gold)
Product code:	R-423-20-C-CE, R-423-25-C-CE
EDMA code:	15-04-80-19
Classification:	Other device (all devices except Annex II and self-testing devices)

We, manufacturer, herewith declare under our sole responsibility that the above-mentioned product meets the provisions of the following EC Council Directives and Standards. All supporting documentation is retained under the premises of the manufacturer.

List of Directive and Standard Applied:

- Directive 98/79/EC
- EN ISO 14971:2012
- EN ISO 13485:2016
- EN 13612:2002/AC:2002
- EN13975:2003
- EN ISO 15223-1:2016
- EN ISO 18113-1:2011
- EN ISO 18113-2:2011
- EN 13641:2002
- EN ISO 23640:2015
- 1272/2008/EC

Place, Date of Issue: Shanghai, P.R. China, 2020-03-09

Signature of RA Director

KHB