Declaration of Conformity

Manufacturer Bioscience（Tianjin）Diagnostic Technology Co.,Ltd
Building No.14,International Medical Equipment Industrial Park, Liujing Road, Dongli Development Area, Tianjin, China

European Representative WellKang Ltd

Product COVID-19 Antibody Diagnostic Kit (Colloidal Gold)
COVID-19 IgG Antibody Diagnostic Kit (Colloidal Gold)
COVID-19 IgM Antibody Diagnostic Kit (Colloidal Gold)
COVID-19 IgG Antibody Diagnostic Kit (CLIA)
COVID-19 IgM Antibody Diagnostic Kit(CLIA)
COVID-19 IgG Antibody Diagnostic Kit (ELISA)
COVID-19 IgM Antibody Diagnostic Kit(ELISA)

Classification Others IVD Devices

Conformity Assessment Route IVD 98/79/EC Annex III

We herewith declare under our sale responsibility that the above mentioned products meet the provisions of the Council Directive 98/79/EC on in vitro diagnostic medical devices. All supporting documents is retained at the premise of the manufacturer.

Standards Applied 98/79/EC EN ISO 13485:2012

CE

Tianjin, China; 9th March 2020

(Place ,Date of issue)

(Signature and Position)

ZERTIFIKAT ◆ CERTIFICATE ◆ 認証証書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

Product Service

CERTIFICATE

No. Q2N 17 07 94804 002

Holder of Certificate: **Bioscience (Tianjin) Diagnostic Technology Co.,Ltd.**

No.201.10 SiWei Road
Dongli District
300300 Tianjin,China
PEOPLE'S REPUBLIC OF CHINA

Facility(ies):

Bioscience (Tianjin) Diagnostic Technology Co.,Ltd.
No.201.10 SiWei Road, Dongli District, 300300 Tianjin,China, PEOPLE'S REPUBLIC OF CHINA

Certification Mark:

TÜV SÜD EN ISO 13485 tuv-sud.com/ps-cert

Scope of Certificate:

Production, Sales, Distribution and Servicing of In-vitro Diagnostic Reagent of Chemiluminescent immunoassay and Chemiluminescent immunoassay analyzer,In-vitro Diagnostic Reagent of Time-resolved fluorescence immunoassay and Time-resolved fluoresc immunoas-say analyzer.

Applied Standard(s):

EN ISO 13485:2012 + AC:2012
Medical devices - Quality management systems - Requirements for regulatory purposes
(ISO 13485:2003 + Cor. 1:2009)
DIN EN ISO 13485:2012

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system (excluding subclause 7.3), which meets the requirements of the listed standard(s). See also notes overleaf.

Report No.: BJ15648012

Valid from: 2017-07-18
Valid until: 2020-07-17

Date, 2017-07-18

Stefan Preiß

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