TÜVRheinland®

Certificate

The Certification Body of
TÜV Rheinland LGA Products GmbH

hereby certifies that the organization

Shenzhen Watmind Medical Co., Ltd.
8th Floor, Building A, No.16-1,
Jinhui Road, Jinsha Community
Kengzi subdistrict, Pingshan District
518118 Shenzhen
P.R. China

has established and applies a quality management system for medical devices for the following scope:

Design and Development, Manufacture and Distribution of in-vitro diagnostic Medical Devices
(see attachment for products and additional sites included)

Proof has been furnished that the requirements specified in

EN ISO 13485:2016

are fulfilled. The quality management system is subject to yearly surveillance.

Effective Date:	2020-12-30
Certificate Registration No.:	SX 60150107 0001
An audit was performed. Report No.:	17054604 003
This Certificate is valid until:	2022-07-03

Certification Body

DAkkS
Deutsche
Akkreditierungsstelle
D-ZM-14169-01-02

TÜV Rheinland LGA Products GmbH
TUVRheinland®
Zertifizierungsstelle

Date 2020-12-30

Wenxiang Zhang

TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg
Tel.: +49 221 806-1371 Fax: +49 221 806-3935 e-mail:cert-validity@de.tuv.com http://www.tuv.com/safety

TÜVRheinland®

Doc. 1/1 Rev. 0

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Attachment to Certificate
Registration No.: SX 60150107 0001
Report No.: 17054604 003

Organization:

Shenzhen Watmind Medical Co., Ltd.
8th Floor, Building A, No.16-1,
Jinhui Road, Jinsha Community
Kengzi subdistrict, Pingshan District
518118 Shenzhen
P.R. China

Scope:

Products:
In-vitro diagnostic analyzers and in-vitro diagnostic test kits used in the diagnosis and quantitive detection of cardiac markers, immune status, Thyroid Functions, Auto-Immune Diseases, Fertility testings, Coagulation and Infectious Diseases including point of care in-vitro diagnostic medical devices

Sites included:
Shenzhen Watmind Medical Co., Ltd.
8th Floor, Building A, No.16-1, Jinhui Road, Jinsha Community, Kengzi subdistrict, Pingshan District, 518118, Shenzhen, China
Manufacture of the a.m. products

Shenzhen Watmind Medical Co., Ltd.
Room 106-1 & 107, Shenzhen IC Design & Application Industrial Park, No.1089 Chaguang Road, Nanshan District, Shenzhen, China
Design and Development and Distribution of the a.m. products

Certification Body

DAkkS
Deutsche Akkreditierungsstelle
D-ZM-14169-01-02

TÜV Rheinland LGA Products GmbH TUVRheinland® Zertifizierungsstelle

Date: 2020-12-30

Wenxiang Zhang

EC Declaration of Conformity

Manufacturer: **Shenzhen Watmind Medical Co., Ltd.**
8th Floor, Building A, No.16-1, Jinhui Road, Jinsha Community, Kengzi Subdistrict, Pingshan District, 518118, Shenzhen, China

EC-Representative: **Shanghai International Holding Corporation GmbH(Europe)**
Eiffestrasse 80, 20537 Hamburg, Germany

We, the manufacturer, herewith declare that the products

SARS-CoV-2 Ag Diagnostic Test kit (Colloidal Gold)
REF: LFA0401-25N

meet the provisions of Directive 98/79/EC which apply to them.

The medical device has been assigned to others according to Directive 98/79/EC. It bears the mark

CE

following the procedure relating to the EC Declaration of Conformity set out in Annex III of Directive 98/79/EC.

Standards Applied: List of (harmonized) standards for which documented evidence for compliance can be provided as attachment.

The above mentioned declaration of conformity is exclusively under the responsibility of

Shenzhen Watmind Medical Co., Ltd.

ShenZhen,China 28th,Jul,2020

Li Quan

Place , date

Legally binding signature, Function
(General Manager)