EC Certificate

TÜVRheinland®

Full Quality Assurance System
Directive 98/79/EC on In Vitro Diagnostic Medical Devices,
Annex IV excluding (4, 6)

Registration No.: HL 2069313-1

Manufacturer: Hangzhou Laihe Biotech Co., Ltd.
Room 505-512, 5th Floor, No.2B Building,
No.688 Bin'an Road, Changhe Street, Binjiang District,
Hangzhou,
310052 Zhejiang
P.R. China

Products: SARS-Cov-2 Antigen Rapid Tests for self-testing

- Novel Coronavirus (COVID-19) Antigen Test Kit (Colloidal Gold) for self-testing

The Notified Body hereby declares that the requirements of Annex IV, excluding sections 4 and 6 of the directive 98/79/EC have been met for the listed products. The above named manufacturer has established and applies a quality assurance system, which is subject to periodic surveillance, defined by Annex IV, section 5 of the aforementioned directive. For placing on the market of List A devices covered by this certificate an EC design-examination certificate according to Annex IV, section 4 and a verification of manufactured products according to section 6 is required.

Report No.: 244336465-200

Effective date: 2021-08-19

Expiry date: 2024-05-26

Issue date: 2021-08-19

TÜV Rheinland LGA Products GmbH Zertifizierungsstelle

Dipl.-Ing. Sven Hoffmann
TÜV Rheinland LGA Products GmbH
Tillystraße 2 · 90431 Nürnberg · Germany

TÜV Rheinland LGA Products GmbH is a Notified Body according to Directive 98/79/EC concerning in vitro diagnostic medical devices with the identification number 0197.

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310052 Zhejiang
P.R. China

The scope of certification includes the following manufacturing sites:

No.	Location	Product groups manufactured
/01	Hangzhou Laihe Biotech Co., Ltd. 3rd, 4th and 5th floors of the west side, No.6 Building, No. 88 Jiangling Road, Xixing Street, Binjiang District, Hangzhou, 310052 Zhejiang P.R. China	SARS-Cov-2 Antigen Rapid Tests for self-testing - Novel Coronavirus (COVID-19) Antigen Test Kit (Colloidal Gold) for self-testing

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