# DECLARATION OF CONFORMITY

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|---|---|
| **MANUFACTURER** | Qingdao Hightop Biotech Co., Ltd.<br>No.369 Hedong Road, Hi-tech Industrial Development Zone,<br>Qingdao, Shandong, 266112, China |
| **EUROPEAN REPRESENTATIVE** | MedNet EC-REP GmbH<br>Borkstrasse 10 · 48163 Muenster · Germany |
| **PRODUCT** | SARS-CoV-2 Antigen Rapid Test<br>--- Analyte: SARS-CoV-2 Antigen |
| **CLASSIFICATION** | Self-testing |
| **CONFORMITY ASSESSMENT ROUTE** | IVDD 98/79/EC Annex Ⅲ section 6 |

WE, THE MANUFACTURER, IS EXCLUSIVELY RESPONSIBLE FOR THE DECLARATION OF CONFORMITY. WE HEREWITH DECLARE THAT THE ABOVE MENTIONED PRODUCTS MEET THE PROVISIONS OF THE COUNCIL DIRECTIVE 98/79/EC. ALL SUPPORTING DOCUMENTATIONS ARE RETAINED UNDER THE PREMISES OF THE MANUFACTURER.

**STANDARDS APPLIED** 98/79/EC, EN ISO 18113-1: 2011, EN ISO 18113-2:2011, EN ISO 18113-4: 2011, EN 13612: 2002, EN ISO 23640: 2015, EN 13641: 2002, EN ISO 15223-1: 2016, EN 13975: 2003, EN ISO 14971: 2019, EN ISO 13485: 2016, EN ISO 17511: 2003, EN 62366-1: 2015, EN 13532: 2002.

**PLACE, DATE OF ISSUE** Qingdao, 2021-06-01

**SIGNATURE**

Mr. Frank Yang

General Manager

CE 1434

DAkkS
Deutsche
Akkreditierungsstelle
D-ZM-11321-01-00

TÜV SÜD
Product Service

# Certificate

## No. Q5 093780 0003 Rev. 00

**Holder of Certificate:** **Qingdao Hightop Biotech Co., LTD**
No. 369 Hedong Road, Hi-tech Industrial Development Zone
266112 Qingdao, Shandong
PEOPLE'S REPUBLIC OF CHINA

**Facility(ies):** Qingdao Hightop Biotech Co., LTD
No. 369 Hedong Road, Hi-tech Industrial Development Zone,
266112 Qingdao, Shandong, PEOPLE'S REPUBLIC OF CHINA

**Certification Mark:**

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

**Scope of Certificate:** **Design and Development, Production, Sales and Distribution of In-vitro Diagnostic of Immunofluorescence kits, Colloidal Gold Chromatography Kits, ELISA Filtration Assay Kits, Dry Chemical Reagents, Biochemical Reagents.**

**Design and Development, Production, Sales, Distribution and Servicing of In-vitro Diagnostic Equipment: Biochemical Analyzer, Urine Analyzer, Microplate Reader, Microplate Washer, Fluorescence Immunoassay Analyzer, Automatic ELISA Filtration Assay Reader.**

**Applied Standard(s):** EN ISO 13485:2016
Medical devices - Quality management systems - Requirements for regulatory purposes
(ISO 13485:2016)
DIN EN ISO 13485:2016

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

**Report No.:** BJ18996041

**Valid from:** 2019-09-06
**Valid until:** 2022-03-31

**Date,** 2019-09-06

Stefan Preiß
Head of Certification/Notified Body


TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

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