



Declaration of Conformity Certificate



Manufacturer: Atlas Link Technology Co., Ltd

Address: Gu'an Road Xing Min, Guan South Industry Zone,
065500 Langfang City, Hebei Province, CHINA
Tel: 86-10-8890 9113 Fax: 86-10-8890 9115
WEB: <https://www.invitro-test.com>

European Representative: MT Promedt Consulting GmbH

Address: Altenhofstrasse 80, 66386 St. Ingbert Germany
TEL: +49-0-6894 581020 FAX: +49-0-6894 581021
E-mail: ear@mt-procons.com

Registered Trademark: FASPIT™

Products: SARS-CoV-2 Antigen Saliva Test Kit
(Colloidal Gold Immunochromatography)

Catalog No.: C2103

Classification: Other IVD Test Device

EDMA code: 15 04 80 90 00

Conformity Assessment Route: Annex III Applied (IVD 98/79/EC)
No. Annex List A+B product, no self-testing Product

Declaration: We herewith declare that the above mentioned products meet the Annex III provisions of the Council Directive 98/79/EC for In Vitro diagnostic medical devices. All supporting documentation is retained under the premises of the manufacturer.

Standard Applied: EN ISO13485:2016, EN ISO14971:2012, EN ISO 18113- 1:2011,
EN ISO 18113-2:2011, EN 13612:2002, EN 13641:2002, EN ISO 15223-1:2016, EN ISO 15223-2: 2010 EN ISO 23640:2015

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General Manager:
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