



DECLARATION OF CONFORMITY

According Directive 98/79/EC on in vitro diagnostic medical devices, Annex III.

Manufacturer: Innovation Biotech (Beijing) Co., Ltd.

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In Vitro Diagnostic Directive:

- Novel Coronavirus (SARS-Cov-2) Antigen Rapid Test Cassette (swab)

Category: Others.

Conformity assessment route: Declaration of Conformity IVD D Annex III.

Applicable Standards:

ISO 13485:2016

ISO 14971:2019

EN ISO 18113-1:2011

EN ISO 18113-2:2011

EN ISO 18113-3:2011

EN 13641:2002

ISO 15223-1:2016

EN 13612:2002

ISO 23640:2015

EN 62366-1:2015

We, the manufacturer, hereby declare with sole responsibility that our product/s mentioned above meet/s the provisions of the Directive 98/79/EC of the European Parliament and of the Council on In Vitro Diagnostic Medical Devices.

We agree to develop, implement and maintain a documented post-production monitoring process.

Signed on: **Name of authorized signatory:**

Position held in the company: General Manager

Place: Beijing, China **Seal/Stamp:**

Innovation Biotech (Beijing) Co., Ltd.

