

EC Declaration of Conformity

No. DOC-COVID- 2001

Manufacturer:

AccuBioTech Co., Ltd.

**Building 10, No.28, Yuhua Road, Beijing, 101300,
China**

whose single Authorized Representative:

Medical Device Safety Service GmbH

**Schiffgraben 41, 30175 Hannover, Germany
DIMDI No.: DE/0000003258**

We, the manufacturer, herewith declare that the products

Accu-Tell[®] COVID-19 IgG/IgM Test

(Model: Cassette)

(including system components and accessories)

*EDMA Product Group: **Other Other Virology - RT & POC***

EDMS Code: 15.70.90.90

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

The medical device has been assigned to devices for other IVD products – Professional Testing Device according to the Directive 98/79/EC. It bears the mark



The product concerned has been designed and manufactured under a quality management system according to Annex III of Directive 98/79/EC.

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

AccuBioTech Co., Ltd.

For and on behalf of
ACCUBIOTECH CO., LTD.

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Authorized Signature(s)

Beijing, March 3, 2020

Place, date

Andy Wang, Managing Director

Legally binding signature, Function