EC Declaration of Conformity

No. DOC-COVID-B352-21/01

Manufacturer:

AccuBioTech Co., Ltd.

Building 4, Maohua Industry Park, No. 1, CAIDA Third Street, Nancai Town, Shunyi District, 101399, Beijing, P.R.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

Product Name: Accu-Tell® COVID-19 IgG/IgM Cassette

Model: Cassette

Catalog Number: ABT-IDT-B352

*(*including system components and accessories*)*

EDMA Product Group: Coronavirus - RT & POC

EDMS Code: 15 70 90 08

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

CE

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.
Authorized Signature(s)

Beijing, Jan.01 , 2022

Place , date

Andy Wang, Managing Director

Legally binding signature, Function