DECLARATION OF CONFORMITY

Manufacturer: 3D Biomedicine Science & Technology Co., Limited.
Address: Block A, Building 2, No.158 Xinjunhuan Road, Minhang District, Shanghai, 201114, China

European Representative: Caretechion GmbH
Address: Niederrheinstr 71, 40474 Duesseldorf, Germany

Product Name: ANDiS FAST SARS-CoV-2 RT-qPCR Detection Kit

Catalog Number: 3103010051/3103010052/3103010069

Packaging Specification: 50Tests/kit, 100Tests/kit

Classification: Other devices, not for self-testing

Assessment route: Annex III (Section 6 is not applicable)

We, the manufacturer, declare the compliance of the above medical device with the applicable requirements of in vitro diagnostic Medical Devices Directive: COUNCIL DIRECTIVE 98/79/EC OF 27 October 1998 CONCERNING in vitro diagnostic MEDICAL DEVICES (IVDD 98/79/EC). The declaration is valid in connection with the release document for the respective batch of produced devices. All the supporting documents and files are retained under the premises of the manufactures.

This declaration of conformity is issued under the sole responsibility of 3D Biomedicine Science & Technology Co., Limited.

Place, Date of Issue: Shanghai, China, Mar 26, 2021

Name: LEI, XIONG

Position: Chief Executive Officer

Signature: