

CE EC DECLARATION OF CONFORMITY CE

Manufacturer: 3D Biomedicine Science & Technology Co., Limited.

Address: Block A, Building 2, No.158 Xinjunhuan Road, Minhang District,
Shanghai, 201114, China

European Representative: MedNet EC-REP GmbH

Address: Borkstrasse 10, 48163 Muenster, Germany

Product Name: 3DMed 2019-nCoV RT-qPCR Detection Kit

Product specification: 100T

Classification: Other devices, not for self-testing

Conformity 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). 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 14th, 2020

Name: LEI, XIONG

Position: Chief Executive Officer

Signature:

