



BOSON

Declaration of Conformity

Manufacturer Xiamen Boson Biotech CO,. Ltd.
90-94 Tianfeng Road, Jimei North Industrial Park,
Xiamen, Fujian 361021, P. R. China.

European Representative Lotus NL B.V.
Koningin Julianaplein 10, 1e Verd, 2595AA,
The Hague, Netherlands.

Device/s Rapid 2019-nCoV IgG/IgM Combo Test Card

Classification Other

Confirmative Assessment Route IVDD 98/79/1998 Annex III

We, Xiamen Boson Biotech Co., Ltd. declare that the above mentioned devices conforms to the relevant provisions of the EC Council Directive 98/79/1998 and is in accordance with the Annex III, ISO 13485:2016 Quality Management System, as implemented by the European Union's Medical Devices Regulations and the Federal and Local Authorities.

Place, Date of Issue Xiamen, 2020-03-05

Signature Changgong Zhang

(Signed By Boson Representative)

Name: Changgong Zhang
Title: General Manager

CE