



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 SARS-CoV-2 Antigen Test Card

Classification Other

Confirmative Assessment Route 98/79/EC Annex III, except
point 6, of Directive

Standard Applied

EN ISO 13485:2016	EN ISO 14971:2019
EN ISO 18113-1:2011	EN ISO 18113-2:2011
ISO 15223-1:2021	EN 13612:2002
EN ISO 23640:2015	EN 13641:2002

We, Xiamen Boson Biotech Co., Ltd. declare that the above mentioned devices conforms to the relevant provisions of the EC Council Directive 98/79 and is in accordance with the Annex III, EN 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, 2022-06-23

Signature Changgong Zhang

(Signed By Boson Representative)

Name: Changgong Zhang
Title: General Manager



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