



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.

Product Rapid SARS-CoV-2 Antigen Test Card
REF: 1N40C5-2, 1N40C5-4, 1N40C5-6
1N40C5-7, 1N40C5-8, 1N40C5-9, 1N40C5-10

Classification Self-Test IVD

Confirmatory Assessment Route Directive 98/79/EC on In Vitro Diagnostic
Medical Devices (IVDD), Annex III section 6

We herewith declare that above mentioned products meet the provisions of the council Directive 98/79/EC for medical devices. All Supporting Documentation is Retained under the premises of the manufacturer. We have sole responsibility for issuing the Declaration of Conformity.

Standard Applied

ISO 13485:2016	EN ISO 14971:2012
EN ISO 18113-1:2011	EN ISO 18113-4:2011
ISO 15223-1:2016	EN 62366-1:2015
EN 13612:2002	EN ISO 23640:2015

Notified Body TÜV SÜD Product Service GmbH, Ridlerstraße 65,
80339 Munich, Germany.
Identification number: 0123

(EC) Certificate(s) No. V9 061317 0006 Rev. 01

Start of CE-Marking 2021-04-01

Place, Date of Issue Xiamen, 2021-11-12

Signature 
(Signed By Boson Representative)
Name: Changgong Zhang
Title: General Manager

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