



## 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**

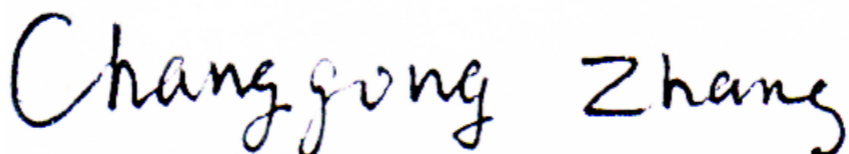
ISO 13485:2016	EN ISO 14971:2012
EN ISO 18113-1:2011	EN ISO 18113-4:2011
ISO 15223-1:2016	EN 62366-1:2015
EN 13612:2002	EN ISO 23640:2015

**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

**CE**  
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