



## Declaration of Conformity

<b>Manufacturer</b>	Xiamen Boson Biotech Co,. Ltd. 90-94 Tianfeng Road, Jimei North Industrial Park, Xiamen, Fujian 361021, P. R. China.
<b>European Representative</b>	Lotus NL B.V. Koningin Julianaplein 10, 1e Verd, 2595AA, The Hague, Netherlands.
<b>Product</b>	Rapid SARS-CoV-2 Antigen Test Card, REF: 1N40C5-2 Rapid SARS-CoV-2 Antigen Test Card, REF: 1N40C5-4 Rapid SARS-CoV-2 Antigen Test Card, REF: 1N40C5-6
<b>Classification</b>	Self-Test IVD
<b>Confirmatory Assessment Route</b>	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.

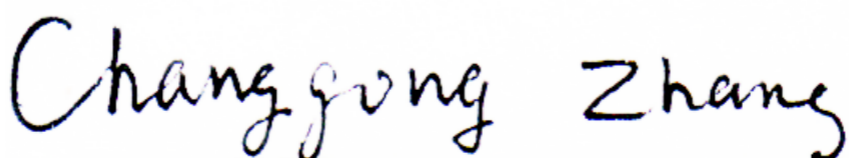
<b>Standard Applied</b>	ISO 13485:2016	EN ISO 14971:2012
	EN ISO 18113-1:2011	EN ISO 18113-4:2011
	ISO 15223-1:2016	EN 62366-1:2015
	EN 13612:2002	EN ISO 23640:2015

<b>Notified Body</b>	TÜV SÜD Product Service GmbH, Ridlerstraße 65, 80339 Munich, Germany. Identification number: 0123
----------------------	---

<b>(EC) Certificate(s)</b>	No. V9 061317 0006 Rev. 00
----------------------------	----------------------------

<b>Start of CE-Marking</b>	2021-04-01
----------------------------	------------

<b>Place, Date of Issue</b>	Xiamen, 2021-04-01
-----------------------------	--------------------

<b>Signature</b>	 (Signed By Boson Representative) Name: Changgong Zhang Title: General Manager
------------------	---

**CE**  
0123