

COVID-19 SELF-TEST ANTIGENICO RAPIDO

Self test antigenico rapido da tampone nasale anteriore

con risultato in 15 minuti.

Registrato al Ministero della Salute (Min.Sal. n° 2089498) e Marcatura CE 0123

(N° certificato: V90613170006 Rev.00 del 01/04/2021)

Sensibilità diagnostica: 96,77%

Specificità diagnostica: 99,20%



Ministero della Salute



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.
Product	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
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. 00
Start of CE-Marking	2021-04-01
Place, Date of Issue	Xiamen, 2021-04-01
Signature	 (Signed By Boson Representative) Name: Changgong Zhang Title: General Manager
CE 0123	