

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: SARS-CoV-2/Flu A+B/RSV Antigen Test Card,
REF: 1N45C5, 1N45C5-1

Classification: Others

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

Standards 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 device 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, 2023-12-25

Signature

Changgong Zhang

(Signed By Boson Representative)

Name: Changgong Zhang

Title: General Manager

