EC Declaration of Conformity

Manufacturer:

Name: Suzhou Soochow University Saier Immuno Biotech Co., Ltd.

Address: No.502 Zhongnan Road, Suzhou Industrial Park, 215123, Suzhou, Jiangsu, China.

Tel: +86-512-62831303

E-mail: Lijun_lu@ saiertech.com

Whose Authorized Representative:

Name: Lotus NL B.V.

Address: Koningin Julianaplein 10,1e Verd, 2595AA, The Hague, Netherlands.

E-mail: peter@lotusnl.com

We, the manufacturer, here with declare that the product(s)

Product Name	InstantSure Covid-19 Ag CARD	**Model /Specification**	1 tests/ kit, 5 tests/ kit, 20 tests/ kit, 50tests/Kit
Intended Use	This kit is used for in vitro qualitative detection of SARS-CoV-2 antigen in human nasopharyngeal Swab, nasal Swab and saliva samples.		
Classification	Others		

Conformity Assessment Route: IVDD98/79/EC Annex III.

Applicable Standards:

ISO 13485:2016
ISO 14971:2019
EN ISO 18113-1:2011
EN ISO 18113-2:2011
EN 13641:2002
ISO 15223-1:2016
EN 13612:2002
ISO 23640:2015
EN 62366-1:2015

CE

We, the manufacturer, here declare with sole responsibility that our product/s mentioned above meet/s the provisions of the Directive 98/79/EC of the European Parliament and of the Council on In-Vitro Diagnostic Medical Devices.

We agree to develop,implement and maintain a documented post-production monitoring process.

Name of General Manager	费敏
Signature	
Date	May.24.2021
Place	Jiangsu, China
Seal (Manufacturer)	