EC Declaration of Conformity

Manufacturer:

Name: Xiamen Biotime Biotechnology Co.,Ltd.

Address:

2F/3F/4F, No.188, Pingcheng South Road, Haicang Street, Haicang District, Xiamen City, Fujian Province, 361026, P. R. China.

Authorized Representative:

Name: Lotus NL B.V.

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

E-mail: peter@lotusnl.com

Tel: +31644168999

We, Xiamen Biotime Biotechnology Co.,Ltd.,hereby declare that the below mentioned medical device meets the provisions of Directive 98/79/EC which apply to them.The declaration of conformity is exclusively under the responsibility of Xiamen Biotime Biotechnology Co.,Ltd.

Product Name	SARS-CoV-2 Antigen Rapid Qualitative Test
Classification	Others

Conformity Assessment Route: IVDD 98/79/EC Annex III.

Applicable Standards:

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

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	Guofeng Zhang
Signature	ZhangGuoFeng
Date	Dec 8,2020
Place	Xiamen
Seal (Manufacturer)	