EC Declaration of Conformity

Manufacturer:
Name: HANGZHOU ALLTEST BIOTECH CO., LTD.
Address: #550, Yinhai Street, Hangzhou Economic & Technological Development Area, Hangzhou -310018, P.R. China

European Representative:
Name: MedNet GmbH
Address: Borkstrasse 10, 48163 Muenster, Germany.

Product Name: COVID-19 Antigen Rapid Test (Oral Fluid)
Model: Cassette
Classification: Self-testing of IVDD 98/79/EC
Conformity Assessment Route: IVDD 98/79/EC Annex III, Article 6
GMDN Code: 65454

We, HANGZHOU ALLTEST BIOTECH CO., LTD, herewith declare that the EC Declaration of Conformity is issued under the sole responsibility of above manufacturer. The above mentioned product is in conformity with following Directives and Standards:

DIRECTIVES

General applicable directives:

DIRECTIVE 98/79/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 27 October 1998 on in vitro diagnostic medical devices.

Standard Applied: EN ISO 13485:2016, EN ISO 14971:2012, EN 13975:2003, EN ISO 18113-1:2011, EN ISO 18113-4:2011, EN 13612:2002/AC:2002, EN ISO 17511:2003, EN ISO 23640:2015, EN 13641:2002, EN 13532:2002, EN ISO 15223-1:2016.

Notified Body: Polish Center for Testing and Certification
Address: 469, Pulawska Street, 02-844 Warsaw, Poland
Notified Body Number: 1434
EC Certificate Number: 1434-IVDD-426/2021
Expire date of the Certificate: 2024-05-27
Start of CE Marking: 2021-05-28

Place, Date of Issue: in Hangzhou on 28/05/2021

Signature:
Name: Gao Fei (Position: General Manager)

Hangzhou AllTest Biotech Co.,Ltd.
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