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 EC-REP GmbH
Address: Borkstrasse 10, 48163 Muenster, Germany

Product Name: SARS-COV-2 and Influenza A+B Antigen Combo Rapid Test (Nasal Swab)
Cat. No.: ISIN-525H
Analyte: Qualitative detection of SARS-CoV-2 Nucleocapsid Protein, Influenza A and Influenza B nucleoproteins antigens present in nasal swab specimen
Model: Cassette
Classification: Self-testing of IVDD 98/79/EC
Conformity Assessment Route: IVDD 98/79/EC Annex III, Article 6
EDMA Code: 15 70 90 90 00

We, HANGZHOU ALLTEST BIOTECH CO., LTD., herewith declare that we are exclusively responsible for this declaration of conformity. We herewith declare that the above mentioned products meet the transposition into national law, the provisions of the following EC Council Directives and Standards. All supporting documentations are retained under the premises of the manufacturer.

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 (CE1434)
Address: 469, Pulawska Street, 02-844 Warsaw, Poland
EC Certificate Number: 1434-IVDD-217/2022
Expire date of the Certificate: 2025-05-27
Start of CE Marking: 2022-05-24

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