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
Cat.No.: ISIC-525
Analyte: SARS-CoV-2 Nucleocapsid protein, Influenza A and Influenza B virus antigens in Nasopharyngeal Swab
Model: Cassette
Classification: Other Device, non-listed in Annex II of IVDD 98/79/EC
Conformity Assessment Route: IVDD 98/79/EC Annex III (Excluding point 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 ISO13485:2016, EN ISO14971:2019, EN 13975:2003, EN ISO 18113-1:2011, EN ISO 18113-2:2011, EN 13612:2002/AC:2002, ISO 17511:2020, EN ISO23640:2015, EN 13641:2002, EN ISO 15223-1:2021

Place, Date of First Issue of DOC in Hangzhou on 05/01/2021
Date of Issue of DOC on 22/02/2022

Signature: _____
Name: GAO FEI (Position: General Manager)

Hangzhou AllTest Biotech Co.,Ltd.
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