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: SARS-CoV-2 Antigen Rapid Test (Nasal Swab)
Model: Cassette
Analyte: SARS-CoV-2 Nucleocapsid protein Antigens in swab specimen
Classification: Self-testing, not listed in Annex II of IVDD 98/79/EC
Conformity Assessment Route: IVDD 98/79/EC, Annex III, section 6
GMDN: 65454

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 corresponding national laws, the provisions of the following EC Council Directives, Standards and Common Technical Specifications. All supporting documentations are retained at 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 ISO 15223-1:2016,EN 13532:2002

Notified body: Polish Center for Testing and certification (CE1434)
(EC) Certificate(s): 1434-IVDD-035/2022
Expire date of the Certificate: 2025-05-27
Start of CE Marking: 2021-07-05
Place, Date of First Issue of DOC: in Hangzhou on 2021-07-05
Date of Issue of DOC on 2022-03-17

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

Hangzhou AllTest Biotech Co.,Ltd.
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