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 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 13532:2002, EN ISO 15223-1:2016.

Notified Body: Polish Center for Testing and Certification,
Notified Body No.: CE1434
Address: 469, Pulawska Street, 02-844 Warsaw, Poland
EC Certificate Number: 1434-IVDD-429/2021
Expire date of the Certificate: 2024-05-27
Start of CE marking: 2021-05-28
Place, Date of First Issue of DOC: in Hangzhou on 2021-05-28
The Date of Issue of DOC on 2021-08-18

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