EC Declaration of Conformity

Manufacturer:
Name：CITEST DIAGNOSTICS INC.
Address：170-422 Richards Street, Vancouver BC V6B 2Z4 Canada

European Representative:
Name: CMC MEDICAL DEVICES & DRUGS, S.L.
Address: C/ HoracioLengo No 18, CP 29006, Málaga-Spain

Product Name: COVID-19 Antigen Rapid Test (Swab)
Model: Cassette
Classification: Self-testing of IVDD 98/79/EC
Conformity Assessment Route: IVDD 98/79/EC Annex III
EDMA Code: 15 70 90 08 00

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.

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 62366:2015, EN 13532:2002

Notified Body: Polish Center for Testing and Certification (CE1434)
Address: 469, Pulawska Street, 02-844 Warsaw, Poland
EC Certificate Number: 1434-IVDD-509/2021
Expire date of the Certificate: 27/05/2024
Start of CE marking: 25/11/2021
Place, Date of First Issue of DOC: in Vancouver on 25/11/2021

CITEST DIAGNOSTICS INC

Signature:
Name: Fu YanPing (Position: General Manager)