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
Model: Cassette
Classification: Other Device of IVDD 98/79/EC
Conformity Assessment Route: IVDD 98/79/EC Annex III
EDMA Code: 15 70 90 90 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.

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 18113-2:2011, EN 13612:2002/AC:2002, EN ISO 17511:2003, EN ISO 23640:2015, EN 13641:2002, EN ISO 15223-1:2016

Place, Date of Issue: in Vancouver on 11/09/2020

CITEST DIAGNOSTICS INC.

Signature: Soar Gao

Name: Soar Gao (Position: General Manager)