

CE EC Declaration of Conformity CE

Manufacturer: Zhuhai Encode Medical Engineering Co., Ltd.
Add: No.020, Honghui 2nd RD Hongqi Industrial
Zone, Jinwan District, Zhuhai, P.R China(519090)

Whose Single Authorized EU-Representative: CMC Medical Devices & Drugs S.L.
Add: C/ Horacio Lengo N° 18, CP 29006, Málaga, Spain

Product Name: SARS-COV-2 Antigen Rapid Test

Classification : **Others of ANNEX II of IVDD**

Conformity Assessment Route: **Annex III**

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:

In Vitro Diagnostic Medical Devices DIRECTIVE 98/79/EC

Harmonized standards:

EN ISO 13485:2016, EN ISO 15223-1:2016, EN ISO 14971:2012, EN 13641: 2002,
EN ISO 18113-1:2011, EN ISO 18113-2:2011, EN 13612: 2002, EN ISO 23640:2015

Signature:

Name:  Sun Yifeng

Title: General manager

Place/Date:  Zhuhai.2020-09-01