

EC DECLARATION OF CONFORMITY

Manufacturer's Name : Taiwan Carbon Nano Technology Corporation.
Business Address : 5F.,No.50-1&50-2,Keyan Rd.,Zhunan Township,
Miaoli County 350401, TAIWAN (R.O.C)

SRN : CE
CND code : W0105040619
Classification : Non A
Product Name : Ainos SARS-CoV-2 Antigen Rapid Test Kit
Model Name/Number : C1925A
European Authorized Representative : CMC Medical Devices & Drugs S.L.
Address : C/ Horacio Lengo N18. CP29006,

EC REP

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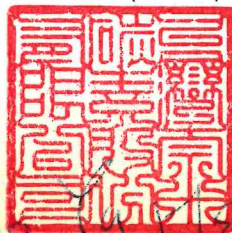
We declare under our sole responsibility that the diagnostic products, classified as "all other IVD Medical Devices" according to Annex IX rules, is in conformity with the following standard(s), normative document(s) and the European Union's Directive 98/79/EC of the European parliament and the council of 27 October 1998 on in vitro diagnostic medical device and are in accordance with the Annex III of the IVDD, as implemented by the European Union's Medical Devices Regulations.

- EN ISO 13485:2016 Medical devices -- Quality management systems -- Requirements for regulatory purposes
- ISO 14971:2019 Medical devices -- Application of risk management to medical devices
- EN ISO 15223-1:2016 Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements (ISO 15223-1:2016, Corrected version 2017-03)
- EN 13612:2002 Performance evaluation of in vitro diagnostic medical devices
- EN 1041:2008+A1:2013/ information supply by the manufacturer of medical devices

The TCNT agrees to develop, implement and maintain a documented post-production experience monitoring process, including the notification of reportable events under the IVDD Vigilance System Guidelines.

The Technical Construction File is maintained at TCNT, Inc. located at 5F, No.50-1 & 50-2 Keyan Rd., Zhuan Township, Miaoli County 350401, TAIWAN (R.O.C)

CE



Liao [Signature]

SIGNATURE

Miaoli County, Taiwan

PLACE

Dec. 23.2020

DATE