

Declaration of Conformity

Manufacturer: Beijing Applied Biological Technologies Co., Ltd.
Room C 101, Building 1, 37 Science Park Road,
Changping District, 102206 Beijing, P.R.China

Manufacturer Address: Building 5 C101, Building 6 504, Building 7 304, No. 97,
Changping Road, Shahe Town, 102206 Beijing, P.R.China

whose single
Authorized EU-
Representative: Luxus Lebenswelt GmbH
Kochstr.1, 47877, Willich, Germany
E-mail: info.m@luxuslw.de

Product Name: SARS-CoV-2 Antigen Rapid Test Cassette

Reference Numbers: CG9011(S)-1T-AN,CG9011(S)-5T-AN,CG9011(S)-10T-
AN,CG9011(S)-20T-AN,CG9011(S)-30T-AN

EDMA CODE: 15.04.09.01

Notify Body: POLISH CENTRE FOR TESTING AND CERTIFICATION

EC Certificate No: 1434-IVDD-511/2021

Classification: **Self-testing**

Conformity Assessment Route: **Annex III - section 6**

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 13612:2002
EN ISO 15223-1:2016	EN ISO 17511:2003
EN ISO 14971:2012	EN ISO 23640:2015
EN 13975:2003	EN 13641:2002
EN ISO 18113-1:2011	EN 62366-1:2015
EN ISO 18113-4:2011	EN ISO 13532:2002

Signature: Zhang Zhiqian

Date: 2021-08-15

Title: General manager

Position: Beijing, China

