CE

EC Declaration of Conformity

in accordance with Directive 98/79/EC

Manufacturer: *Zhejiang Anji Saianfu Biotech Co.,Ltd*
2nd Floor,No 3 Factory, No 489 WenYun Road,TangPu Industrial Park,Dipu Subdistrict, Anji county, HuZhou City, ZheJiang Province,P.R. China

Product/s: *COVID-19 Antigen Rapid Test Kit*
Model: *Cassette*
Category: *Other*
Conformity assessment route: *Annex III (EC DECLARATION OF CONFORMITY)*

Applicable Standards:

EN ISO 13485:2016	Medical devices - Quality management systems - Requirements for regulatory purposes (ISO 13485:2016)EN ISO 13485:2016/AC:2018
EN ISO 14971:2012	Medical devices - Application of risk management to medical devices (ISO 14971:2007, Corrected version 2007-10-01)
EN ISO 18113-1:2011	In vitro diagnostic medical devices - Information supplied by the manufacturer (labelling) - Part 1: Terms, definitions and general requirements (ISO 18113-1:2009)
EN ISO 18113-2:2011	In vitro diagnostic medical devices - Information supplied by the manufacturer (labelling) - Part 2: In vitro diagnostic reagents for professional use
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 62366:2008	Medical devices - Application of usability engineering to medical devices
EN 13612:2002	Performance evaluation of in vitro diagnostic medical devices
EN 13641:2002	Elimination or reduction of risk of infection related to in vitro diagnostic reagents
EN 13975:2003	Sampling procedures used for acceptance testing of in vitro diagnostic medical devices - Statistical aspects
EN ISO 17511:2003	In vitro diagnostic medical devices - Measurement of quantities in biological samples - Metrological traceability of values assigned to calibrators and control materials (ISO 17511:2003)
EN ISO 23640:2015	In vitro diagnostic medical devices - Evaluation of stability of in vitro diagnostic reagents (ISO 23640:2011)

We, the Manufacturer, herewith declare with sole responsibility that our product/s mentioned above meet/s the provisions of the Directive 98/79/EC of the European Parliament and of the Council on In-Vitro Diagnostic Medical Devices.

We hereby explicitly appoint **Lotus NL B.V. located at KoninginJulianaplein 10, 1e Verd, 2595AA, The Hague, Netherlands.** to act as our European Authorised Representative as defined in the aforementioned Directive.

Signed on 07 /(Day)/ 08 /(Month) of 2020 /(Year).
Place Anji, Zhejiang, China
Represented by

Signature:
Name of authorized signatory: Wang Qin
Position held in the company: General Manager
Seal/Stamp: