CE Declaration of Conformity CE

According to the In-vitro Diagnostic Medical Device Directive 98/97/EC

Manufacturer: Hangzhou Testsea Biotechnology Co.,Ltd

Address: Building 6 No. 8-2 Scien-tech Road , Yuhang Street, Hangzhou 311121, China

Authorized Representative: Lotus NL B. V.

Address: Koningin Julianaplaein 10, le Verd, 2595AA, The Hague, Netherlands

Product: SARS-CoV2(COVID-19)IgG/IgM Test Cassette (Whole Blood/Serum/Plasma)

Model:SARS-COV-2-IgG/IgM

Classification:Other IVD

The manufacture, herewith, declares that the product as specified above meets the applicable provisions of the follow the Directive and standards and fulfil the obligations imposed by AnnexIII of Directive 98/97/EC. All supporting documentations is retained under the premise of authorized representative.

Directive:

In vitro Diagnostic Medical Device Directive: DIRECTIVE 98/97/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of October 1998 on invitro diagnostic medical device.

Standard:

All application harmonized standards(published in the Official Journal of the European Communities on 17th November 2017)

The above declaration of conformity is issued under the sole responsibility of the manufacture.

2020.02.25

(Place and Date of Issue)

Signed for and on behalf of the manufacture

Wanny Shang

(Signature and Position)

杭州泰熙生物技术有限公司

HANGZHOU TESTSEA BIOTECHNOLOGY CO., LTD