

# MANUFACTURER DECLARATION

25<sup>th</sup>, April, 2021

Subject: Declaration of Identical Product

TO WHOM IT MAY CONCERN,

We undersigned, **Zhejiang Anji Saianfu Biotech Co., Ltd.**, an IVD manufacturer having its headquarters in No.3 Factory, No.489 Wenyun Road, Tangpu Industrial Park, Dipu Subdistrict, Anji Country, Huzhou, Zhejiang, China, here declare that the products listed below in the table are all manufactured by us, they are originally repacked from reOpenTest COVID-19 Antigen Rapid Test, which has been validated by Germany P.E.I,

P.E.I Reference Link:

[https://www.pei.de/SharedDocs/Downloads/EN/newsroom-en/dossiers/evaluation-sars-cov2-antigen-tests-overview-04-12-2020.pdf?\\_\\_blob=publicationFile&v=9](https://www.pei.de/SharedDocs/Downloads/EN/newsroom-en/dossiers/evaluation-sars-cov2-antigen-tests-overview-04-12-2020.pdf?__blob=publicationFile&v=9)

**Both of them have the same performance on nasal swab specimens, they are identical.**

Product	Certificate
reOpenTest COVID-19 Antigen Rapid Test	CE-IVD For professional use
reOpenTest COVID-19 Antigen Rapid Test	Self-Test / BfArM 5640-S-285/21
AndLucky SARS-CoV-2 Antigen Rapid Test	Self-Test / BfArM 5640-S-064/21

\*BfArM approval link: [https://www.bfarm.de/DE/Medizinprodukte/Antigentests/Antigen-Tests\\_zur\\_Eigenanwendung.html](https://www.bfarm.de/DE/Medizinprodukte/Antigentests/Antigen-Tests_zur_Eigenanwendung.html)

Your Sincerely,

  
Signature/Star

CEO / Qian Wang



**reOpenTest**

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