# EC Declaration of Conformity

in accordance with Directive 98/79/EC

## Manufacturer:

***Name:*** *Hangzhou Realy Tech Co., Ltd.*
***Address:*** *#2 Building, No. 763, Yuansha Village, Xinjie Street, Xiaoshan District, 311200 Hangzhou City, Zhejiang Province, PEOPLE'S REPUBLIC OF CHINA*

| *Product/s* | *Catalogue number* |
|---|---|
| SARS-Cov-2 & Influenza A/B Combo Rapid Test Cassette (swab) | K751416D |

*Category: Self-testing*

*Conformity assessment route:Directive 98/79/EC on In Vitro Diagnostic Medical Device（IVDD）,Annex III （6）*

*Notified Body：CeCert Spółka z ograniczoną odpowiedzialnością*
*ul. Żurawia 32/34 apt 49, 00-515 Warsaw*
*notified under No.2934 to the EC Commission*

*Applicable Standards: EN ISO 13485:2016, EN ISO 15223-1:2021,EN ISO 13612:2002,EN ISO 18113-1:2011,EN ISO 18113-3:2011,EN ISO 18113-4:2011,EN ISO 23640:2015,EN ISO 14971:2019,EN 62366-1:2015, ISO 20916:2019,MEDDEV 2.12-1 rev 8,MDCG 2021-21.*

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 Koningin Julianaplein 10, 1e Verd, 2595AA, The Hague, Netherlands to act as our European Authorised Representative as defined in the aforementioned Directive.

Hang Zhou 2022.5.5

(Place and date of issue)

Dean

(Signature and position)

Signed for and on behalf of the manufacturer