V6.3a

CE

EC Declaration of Conformity

according to the Directive 98/79/EC

(applicable to **Others/General** *IVD* Devices only)

Manufacturer: Company Name: Nanjing Liming Bio-Products Co., Ltd.
Address: No. 12, Huayuan Road, Nanjing, Jiangsu, 210042.
P.R. China

Product/s: StrongStep® SARS-CoV-2 lgM/lgG Antibody Rapid Test (Cat. No. 502090)

Model: 20 Tests/Box

Category: **Others/General**

Conformity assessment route: **Annex III, except point 6, of Directive (**Module **A)**

Applicable Standards:

EN ISO 18113-1:2011	EN ISO18113-2:2011	EN 13612:2002
EN ISO 23640:2015	EN 13641:2002	EN ISO 14971:2012
EN ISO 15223-1:2016	EN ISO 13485:2016	EN 13975:2003

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 Wellkang Ltd t/a Wellkang Tech Consulting located at 16 Castle St,Dover, Kent, CT16 1PW,England,UK to act as our European Authorised Representative as defined in the aforementioned Directive.

Signed on 27/(Day)02/(Month) of 2020. Place: Nanjing

Represented by: Zhang Shuwen

Signature (on behalf of the manufacturer) Zhang Shuwen

Full Name of authorized signatory: Zhang Shuwen
Position held in the company: President

Company Seal/Stamp: