



《EC Declaration of Conformity》
According to the Directive 98/79/EC
(Applicable to **Others/General** IVD Devices only)

Manufacturer:

Name: Dynamiker Biotechnology (Tianjin) Co., Ltd.

Address: No.14 Building, Eco-Business Park, 2018 Zhongtian Avenue, Sino-Singapore
Tianjin Eco-City, Tianjin 300467, China

Product/s: Dynamiker SARS-CoV-2 Ag Rapid Test

Model: DNK-1425-1

Category: **Others/General**

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

Applicable Standards:

ISO/IEC Directives–Part 2: 2004

ISO 13485:2016

ISO 2859–1:1999,

EN ISO 13485:2016

ISO 780:1997

WS/T 124–1999

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 Authorized Representative as defined in the aforementioned Directive.

Signed this Day/ 15 of Month/ 09 of Year/ 2020 , Place (Tianjin),
PR China

Represented by:

Signature (on behalf of the manufacturer) :

Full Name of authorized signatory: ZHOU ZEQI

Position held in the company: President

Company Seal/Stamp:

