CE

《EC Declaration of Conformity》

According to the Directive 98/79/EC
(Applicable to **Others** IVD Devices only)

Manufacturer:

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

Address: No.2 Building, Rongzhi Industry Park, No. 3667, Zhongbin Avenue, Sino-Singapore Eco-city, TEDA, Tianjin300467, China

Product/s: QuicG™ Fungus (1-3)-β-D-Glucan Lateral Flow Assay

Category: 1 test/bag, 20 tests/kit, 40 tests/kit, 50 tests/kit, 100 tests/kit

Catalogue No.: DNK-2301-1

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

Applicable Standards:

ISO 2859–1:1999, EN ISO 13485: 2016, ISO 15223-1:2021

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 Julianaplei 10, 1e Verd, 2595AA, The Hague, Netherlands** to act as our European Authorized Representative as defined in the aforementioned Directive.

Signed this Day/ 24 of Month/ 05 of Year/ 2022 , 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:

Dynamiker Biotechnology (Tianjin) Co., Ltd. 丹娜（天津）生物科技股份有限公司