



## 《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: Carbapenem Resistant Enterobacteriaceae Test Kit (LFA)

Model: 40 tests; 40 tests (C); 40 tests (D)

Catalogue No.: DNK-2302-1

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 **Riomavix S.L.** located at **Calle de Almansa 55, 1D, Madrid 28039 Spain** to act as our European Authorized Representative as defined in the aforementioned Directive.

Signed this Day/ 24 of Month/ 5 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:

