CE

DECLARATION OF CONFORMITY

According Directive 98/79/EC on in vitro diagnostic medical devices, Annex III.

Manufacturer: Tianjin Galenus Medical Co., Ltd.

Address: Room 403, 4th Floor, Building C02, Pioneering Headquarters Base, Wuqing District, Tianjin, P. R. China

European Representative: Riomavix S.L.

Address: Calle de Almansa 55, 1D, Madrid 28039 Spain

Tel.: +34 658 396 230

E-mail: leis@riomavix.com

In Vitro Diagnostic Directive:

- **Rapid Urease Test**

Category: Others.

Conformity assessment route: Declaration of Conformity IVDD Annex III

Applicable Standards:

ISO 13485:2016	*EN ISO 18113-3:2011*	*EN 13612:2002*
ISO 14971:2019	*EN 13641:2002*	*ISO 23640:2015*
EN ISO 18113-1:2011	*ISO 15223-1:2016*	*EN 62366-1:2015*
EN ISO 18113-2:2011		

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 agree to develop, implement and maintain a documented post-production monitoring process.

Signed on

Place: Tianjin, China

Name of authorized signatory: Yinjihui

Position held in the company: General Manager

Seal/Stamp:

Tianjin Galenus Medical Co., Ltd.

Tianjin Galenus Medical Co., Ltd.

Digitally signed by Jighili Tatiana
Date: 2024.03.07 14:13:05 EET
Reason: MoldSign Signature
Location: Moldova