



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:

- HBsAg/HCV/HIV/Syphilis combo Rapid Test(Whole Blood/Serum/Plasma)

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

Name of authorized signatory:

Yinjihui

Position held in the company: General Manager

Place: Tianjin, China

Seal/Stamp:

Tianjin Galenus Medical Co., Ltd.

