

EC Declaration of Conformity

Manufacturer: Shijiazhuang Hipro Biotechnology Co., Ltd
No. 3 Building, Block C, Fangyi Science Park, No. 365 Huai'an East
Road, Hi-tech Zone, Shijiazhuang, Hebei, China

European
Representative: Riomavix Sociedad Limitada
Calle de Almansa 55, 1D, Madrid 28039 Spain
leis@riomavix.com
Product Name: Carbohydrate Antigen 19-9 Test Kit (Nephelometry Immunoassay
Method)

Classification: **Others of ANNEX II of IVDD**

Conformity Assessment Route: **Annex III**

We herewith declare that the above mentioned products meet the transposition into national law, the provisions of the following EC Council Directives and Standards. All supporting documentations are retained under the premises of the manufacturer.

General Applicable Directives:

In Vitro Diagnostic Medical Devices DIRECTIVE 98/79/EC

Harmonized Standards:

EN ISO 13485:2016

EN ISO 15223-1:2021

EN ISO 14971:2019

EN ISO 18113-2:2011

EN 13612:2002

EN ISO 17511:2021

EN ISO 23640:2015

Signature: WEINA ZHENG

Title: General Manager

City: Shijiazhuang

Date: April 8, 2024

