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:	Carcinoem bryonic antigen 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

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Signature: WEINA ZHENG

石家庄禾柏生物技术股份有限公司
Shijiazhuang Hipro Biotechnology Co.,Ltd

Title: General Manager

City: Shijiazhuang

Date: April 8, 2024