

# ***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:** Homocysteime Test Kit (Enzyme Cycling 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



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**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:** D-Dimer 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

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EN 13612:2002

EN ISO 17511:2021

EN ISO 23640:2015

**Signature:** WEINA ZHENG

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**Date:** April 8, 2024



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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:** Luteinizing Hormone Test Kit (Fluorescence 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



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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:** Procalctionin Test Kit (Rate Scattering Turbidimetric 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



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**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:** Follicle Stimulating Hormone Test Kit (Fluorescence 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



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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: Amino-terminal pro-brain natriuretic peptide Test Kit (Immune Fluorescence  
Detection 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



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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

Product Name: Folic Acid Test Kit (Fluorescence 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



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**European Representative:** Riomavix Sociedad Limitada  
Calle de Almansa 55, 1D, Madrid 28039 Spain  
leis@riomavix.com

**Product Name:** Alpha-Fetoprotein Test Kit(Rate Scattering Turbidimetric 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



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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

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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:** Vitamin B12 Test Kit (Fluorescence 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

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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:** High sensitivity C-reactive Protein 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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**European Representative:** Riomavix Sociedad Limitada  
Calle de Almansa 55, 1D, Madrid 28039 Spain  
leis@riomavix.com

**Product Name:** Cardiac Troponin I Test Kit (Rate Scattering Turbidimetric 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

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EN 13612:2002

EN ISO 17511:2021

EN ISO 23640:2015

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**City:** Shijiazhuang

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**European Representative:** Riomavix Sociedad Limitada  
Calle de Almansa 55, 1D, Madrid 28039 Spain  
leis@riomavix.com

**Product Name:** Testosterone Test Kit (Fluorescence 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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**Title:** General Manager

**City:** Shijiazhuang

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**European Representative:** Riomavix Sociedad Limitada  
Calle de Almansa 55, 1D, Madrid 28039 Spain  
leis@riomavix.com

**Product Name:** 25-hydroxy-Vitamin D Test Kit (Immune Fluorescence Detection Method)

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

**Conformity Assessment Route:** **Annex III**

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**General Applicable Directives:**  
In Vitro Diagnostic Medical Devices DIRECTIVE 98/79/EC

**Harmonized Standards:**

EN ISO 13485:2016

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EN ISO 14971:2019

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EN 13612:2002

EN ISO 17511:2021

EN ISO 23640:2015

**Signature:** WEINA ZHENG

**Title:** General Manager

**City:** Shijiazhuang

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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  
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EN ISO 23640:2015

Signature: WEINA ZHENG

Title: General Manager

City: Shijiazhuang

Date: April 8, 2024



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**European Representative:** Riomavix Sociedad Limitada  
Calle de Almansa 55, 1D, Madrid 28039 Spain  
leis@riomavix.com

**Product Name:** Anti-Cyclic Peptide Containing Citrulline Antibody Test Kit (Rate Scattering Turbidimetric 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

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EN ISO 14971:2019

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EN 13612:2002

EN ISO 17511:2021

EN ISO 23640:2015

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**European Representative:** Riomavix Sociedad Limitada  
Calle de Almansa 55, 1D, Madrid 28039 Spain  
leis@riomavix.com

**Product Name:** Microalbuminuric 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

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EN ISO 14971:2019

EN ISO 18113-2:2011

EN 13612:2002

EN ISO 17511:2021

EN ISO 23640:2015

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