

# ***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:** Calprotectin 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

