

# ***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  
Tel: +86 400-019-1606  
Riomavix Sociedad Limitada  
European Representative: Calle de Almansa 55, 1D, Madrid 28039 Spain  
leis@riomavix.com

Product Name: Fecal Occult Blood / Transferrin Combo Test Kit

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: May 25, 2022