

NOTIFICATION OF REGISTRATION

This is to certify that, according to the European Council Directive 98/79/EC, Riomavix S.L. performed all notification duties and responsibilities as the European Authorized Representative:

MANUFACTURER: Shijiazhuang Hipro Biotechnology Co., Ltd.

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

The manufacturer has provided Riomavix S.L. with all the appropriate declaration according to the European Council Directive 98/79/EC including the Declaration of Conformity confirming that its in vitro diagnostic medical device, as stipulated here below, is fulfilling the essential requirements of the European Council Directive 98/79/EC.

IVD Devices: Carbohydrate Antigen I9-9 Test Kit(Nephelometry Immunoassay Method)

Classification: Others

Where the manufacturer affix the CE mark to the device listed they must ensure that all the essential requirements of European Council Directive 98/79/EC are met.

The notification of abovementioned device has been completed by the European Authorized Representative in Spain. The Spain Competent Authority is notified of the manufacture's device and has allocated registration. The registration number is **RPS/1087/2024**



Issue date: 26/Apr/2024
Cert. No.: R20230311-70

