

NOTIFICATION OF REGISTRATION

This is to certify that, according to the European Council Regulation (EU)2017/746 Riomavix S.L. performed all notification duties and responsibilities as the European Authorized Representative:

MANUFACTURER: Infitek Co., Ltd.

ADDRESS: Rm. 2014, Bldg. 3, Ligaoguojihuayuan, No. 1222, West Aoti Road, Lixia District, Jinan, Shandong, China

The manufacturer has provided Riomavix S.L. with all the appropriate declaration according to the European Council Regulation (EU)2017/746 including the Declaration of Conformity confirming that its in vitro diagnostic medical device, as stipulated here below, is fulfilling the General Safety and Performance Requirements of the European Council Regulation (EU)2017/746.

IVD Devices: Biochemistry Analyzer

Classification: Class A

Where the manufacturer affix the CE mark to the device listed they must ensure that all the essential requirements of European Council Regulation (EU)2017/746 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/4788/2022**



Issue date: 08/Aug/2023
Cert. No.: R20230807-1

