Declaration of Conformity

According to Art. 17 of Regulation 2017/746 (EU) on in vitro diagnostic medical devices

Manufacturer: E-LAB Biological Science & Technology Co., Ltd.(CN-MF-000020119)

Address: No.1 Kechuang Road,Yaohua Street, Qixia District, Nanjing City, Jiangsu Province, 210046, China

Authorised Representative: Riomavix S.L.(ES-AR-000001202)

Address: Calle de Almansa 55, 1D, Madrid 28039 Spain

Tel.: +34 658 396 230

E-mail: riomavix@gmail.com

Bsaic UDI: 697517840003M3

Product: Auto Hematology Analyzer

Model: EC-20, EC-21, EC-28, EC-30, EC-31, EC-36, EC-38A, EC-38B, EC-38

Classification: Class A , according to Rule 5 of IVDR Annex VIII

We, manufacturer, herewith declare under our sole responsibility that the above-mentioned product meets the provisions of the following EC Council Directives and Standards. All supporting documentation is retained under the premises of the manufacturer.

List of Directive and Standard Applied:

EN ISO 14971:2019	EN ISO 13485:2016	ISO 15223-1:2021
EN ISO 18113-1:2011	EN ISO 18113-2:2011	IEC 61010-1:2017
IEC61010-2-101:2018	IEC 61326-1:2020	IEC61326-2-6:2020
IEC 62366-1:2015		

Nanjing March 21, 2022

(Place and Date of Issue)

General Manager:

(Signature and Position)

Signed for and on behalf of the Manufacturer