



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)

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Bsaic UDI: 697517840002LZ

Product: Semi-Auto Chemistry Analyzer

Model: ES-90, ES-90C, ES-100C, ES-100P, ES-101C, ES-102, ES-103, ES-104,
ES-105, ES-106

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 18113-3:2011

IEC 61010-1:2017

IEC61010-2-101:2018

IEC61326-1:2020

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