

EC Declaration of Conformity

Certificate No.: EU202005036

Manufacturer: **ARI Medical Technology Co., Ltd.**
Address: **Block C, CC Park, No. 728 Lanzhou Road, Baohe Industrial Zone, Hefei City, Anhui, China**
Products: **Coagulation Analyzer**
Model: **AR-C51, AR-C52, SF-8050, AR-5001, AR-5002, AR-5004, SF-8050**

According to EC Declaration of Conformity set out in Annex VII of the Council Directive 93/42/EEC (MDD93/42/EEC) concerning medical devices.
We herewith declare that the above mentioned products meet the transposition into national law, the essential requirements set out in the Council Directive 93/42/EEC (MDD93/42/EEC) Annex VII.
The manufacturing site for the above products comply with EN ISO13485:2016 Quality Management System Requirements for Medical Devices.

UMDNS No: **15552**

Risk Class: **II**

Applied harmonized standards, national standards or other normative documents
Medical Devices - Quality Management Systems ISO 13485:2016

Identification: **CE**

Place of Issue: Hefei, Anhui.

Date of Issue: 2021-07-01

Valid Until: 2023-07-01

Signature and Stamp:

