

EC Declaration of Conformity

Certificate No.: EU202005068

Manufacturer: **ARI Medical Technology Co., Ltd.**
Address: **Block C, CC Park, No. 728 Lanzhou Road, Baohe Industrial Zone, Hefei City, Anhui, China**
Products: **ECG machine**
Model: **ECG-C01, ECG-C01G, ECG-C03B, ECG-C03G, ECG-C03W, ECG-3, ECG-6, ECG-12, ECG-C06B, ECG-C06G, ECG-C12B, ECG-C12G, ECG-C12W, VECG-C01G, VECG-C03G, VECG-C06G, 8000S, TLC5000**

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: 11379

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: 2022-07-01

Valid Until: 2024-07-01

Signature and Stamp:

