

EC Declaration of Conformity

Certificate No.: EU202005096

Manufacturer: **ARI Medical Technology Co., Ltd.**

Address: **Block C, CC Park, No. 728 Lanzhou Road, Baohe Industrial Zone, Hefei City, Anhui, China**

Products: **Fetal Monitor**

Model: **AFM-300P2, AFM-600P1, AFM-600P2, AFM-800, AFM-800P**

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: **11696**

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:

