EC Declaration of Conformity

Certificate No.: EU202105193

Manufacturer: ARI Medical Technology Co., Ltd.

Address: Block C, CC Park, No. 728 Lanzhou Road, Baohe Industrial

Zone, Hefei City, Anhui, China

Products: Patient Monitor

Model: ARI-800C, ARI-800D, ARI-800E, ARI-800F, ARI-800B+,

ARI-800I, AM-I, AM-IA, AM-8, AM-10, AM-12, AM-15,

M-8000E, M-8000S, M-9000E, M-9000S, VET-2000V,

VET-5000V

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: 16484

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: