EC Declaration of Conformity

Certificate No.: EU202005078

Manufacturer: ARI Medical Technology Co., Ltd.

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

Zone, Hefei City, Anhui, China

Products: Electrosurgical Unit

Model: ESU-350A, ESU-300B, ESU-2000AI, ESU-2000A,

ESU-L2000

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: 11490

Risk Class: III

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: 2020-07-01

Valid Until: 2021-07-01

Signature and Stamp:

