EC Declaration of Conformity

Manufacturer:

whose single Authorized Representative:

DM Systems (Beijing) Co., Limited Suite 1102, Beikong Science Building, 2# Building, No.10, Baifuquan Road, Changping Science Park, Beijing, 102200, China ADVANCED MEDICAL SYSTEMS S.L. CALLE VALENCIA, 25, 1°8,28012-MADRID, SPAIN

We, the manufacturer, herewith declare that the products

ECG Acquisition Systems

Model: (DMS 300-BTT02)

UMDNS-Code: 11-411

meet the provisions of Directive 93/42/EEC which apply to them.

The medical device has been assigned to class IIa according to Annex IX of the Directive 93/42/EEC. It bears the mark

C € 0197

The product concerned has been manufactured under a quality management system according to Annex V of Directive 93/42/EEC.

Compliance of the designated product with the Directive 93/42/EEC has been assessed and certified by the Notified Body

TÜV Rheinland LGA Products GmbH Tillystraße 2, 90431, Nürnberg, Germany

> Certificate No.: DD 60142530 0001 Issue date: 2019-09-06 Expiry date: 2024-05-27

following the procedure relating to the EC Declaration of Conformity set out in Annex V of Directive 93/42/EEC.

This Declaration of Conformity covers all medical devices as specified in the product list belonging to this declaration and is only valid in connection with a batch specific Certificate of Compliance for all products concerned bearing the CE mark.

The above mentioned declaration of conformity is exclusively under the responsibility of

Company: DM Systems (Beijing) Co. Limited
Address: Suite 1102, Beikong Science Building, 2# Building, No.10, Baifuquan Road,
Changping Science Park, Beijing, 102200, China

Beijing 2019. 9. 10.

EC Declaration of Conformity DMSC-02-CE-06-04(V2.0)

Legally binding signature, Function