EC Certificate

Directive 93/42/EEC Annex V
Production Quality Assurance
Medical Devices

Registration No.: DD 60142530 0001

Report No.: 16803452 009

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

Products: Bluetooth ECG Transmitter and Receiver, Holter Recorder, ECG Acquisition Systems, Ambulatory Blood Pressure Monitors

Replaces Approval, Registration No.: DD 60094673 0001

Expiry Date: 2024-05-17

The Notified Body hereby declares that the requirements of Annex V of the directive 93/42/EEC have been met for the listed products. The above named manufacturer has established and applies a quality assurance system, which is subject to periodic surveillance, defined by Annex V, section 4 of the aforementioned directive. For placing on the market of class IIb and class III devices covered by this certificate an EC type-examination certificate according to Annex III is required.

Notified Body

Effective Date: 2019-09-06

Date: 2019-09-06

Jing Zhang

TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg
TÜV Rheinland LGA Products GmbH is a Notified Body according to Directive 93/42/EEC concerning medical devices with the identification number 0197.