Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
ZLG-BS-244.10.08

Product Service

EC Certificate

Full Quality Assurance System
Directive 93/42/EEC on Medical Devices (MDD), Annex II excluding (4)
(Devices in Class IIa, IIb or III)

No. G1 046135 0045 Rev. 00

Manufacturer:

Bionet Co., Ltd.
5F, 61 Digital-ro 31-gil Guro-gu
Seoul 08375
REPUBLIC OF KOREA

Product Category(ies): **Design and Development, Production and Distribution of Syringe Pumps, ECG Recorders, Pocket Dopplers, Fetal Monitors, Spirometers, Patient Monitors, Fetal Monitoring Central System, Patient Monitoring Central System, Pulse Oximeters and Ultrasound Imaging System**

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for design, manufacture and final inspection of the respective devices / device categories in accordance with MDD Annex II. This quality assurance system conforms to the requirements of this Directive and is subject to periodical surveillance. For marketing of class III devices an additional Annex II (4) certificate is mandatory. See also notes overleaf.

Report No.: 74956550

Valid from: 2020-04-02
Valid until: 2024-05-26

Date, 2020-04-02

Christoph Dicks
Head of Certification/Notified Body

ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

A4 / 07.17