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

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 17 11 46135 041**

**Manufacturer:**

**Bionet Co., Ltd.**
5F, Shinsegae I&C Digital Center
61 Digital-ro 31-gil Guro-gu
Seoul 08375
REPUBLIC OF KOREA

**EC-Representative:**

**MGB Endoskopische Geräte GmbH Berlin**
Schwarzschildstr. 6
12489 Berlin
GERMANY

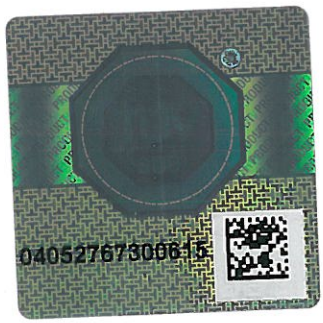
**Product Category(ies):**

**Syringe Pumps, ECG Recorders, 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.:** 74947673

**Valid from:** 2018-01-23
**Valid until:** 2020-06-26




**Date,** 2018-01-23

Stefan Preiß

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

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

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**(Devices in Class IIa, IIb or III)**

## No. G1 17 11 46135 041

**Facility(ies):**

Bionet Co., Ltd.
#903, Shinil IT uto, 13, LS-ro, Gunpo-Si, Gyeonggi-Do 15843,
REPUBLIC OF KOREA

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





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