



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 15 04 46135 034**

Manufacturer:**Bionet Co., Ltd.**

#1101 11F E&C Venture Dream Tower3
38-21, Digital-Ro, 31-Gil
Guro-Gu
Seoul 152-719
REPUBLIC OF KOREA

EC-Representative:**MGB Endoskopische Geräte GmbH Berlin**

Schwarzschildstr. 6
12489 Berlin
GERMANY

Product**Category(ies):**

**Syringe Pumps, ECG Recorders, Pocket Dopplers,
Fetal Monitors, Spirometers, Patient Monitors,
Fetal Monitoring Central System,
Patient Monitoring Central System 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.:

74941417

Valid from:

2015-06-27

Valid until:

2020-06-26

Hans-Heiner Junker

**Date,** 2015-06-24

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

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(Devices in Class IIa, IIb or III)****No. G1 15 04 46135 034****Facility(ies):**

Bionet Co., Ltd.
#801, #802, #803, Shinil IT UTO, LS-Ro 13, Gunpo-Si,
Gyeonggi-Do 435-030, REPUBLIC OF KOREA

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