ZERTIFIKAT ◆ CERTIFICATE ◆ 認証証書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

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

Date, 2015-06-24

Hans-Heiner Junker

656062

Digitally signed by Grabazei Alexandru
Date: 2019.03.05 14:19:45 EET
Reason: MoldSign Signature
Location: Moldova

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

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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

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

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