



# Certificate

No. Q5 046135 0046 Rev. 00

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

**Certification Mark:**



**Scope of Certificate:** **Design and Development, Production and Distribution of ECG Recorders, Fetal Monitors, Spirometers, Patient Monitors, Fetal Monitoring Central System, Patient Monitoring Central System and Pulse Oximeters**

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system, which meets the requirements of the listed standard(s). All applicable requirements of the testing and certification regulation of TÜV SÜD Group have to be complied with. For details and certificate validity see: [www.tuvsud.com/ps-cert?q=cert:Q5 046135 0046 Rev. 00](http://www.tuvsud.com/ps-cert?q=cert:Q5_046135_0046_Rev._00)

**Report No.:** 74959248

**Valid from:** 2021-08-01

**Valid until:** 2024-07-31

**Date,** 2021-07-28



Christoph Dicks  
Head of Certification/Notified Body

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## Applied Standard(s):

EN ISO 13485:2016  
Medical devices - Quality management systems -  
Requirements for regulatory purposes  
(ISO 13485:2016)  
DIN EN ISO 13485:2016

## Facility(ies):

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

Production of ECG Recorders, Fetal Monitors, Spirometers,  
Patient Monitors, Fetal Monitoring Central System, Patient  
Monitoring Central System and Pulse Oximeters

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

Design and Development and Distribution of ECG Recorders,  
Fetal Monitors, Spirometers, Patient Monitors, Fetal Monitoring  
Central System, Patient Monitoring Central System and Pulse  
Oximeters

Bionet Co., Ltd.  
#401, 34, LS-ro 91beon-gil, Dongan-gu, Anyang-si, Gyeonggi-Do  
14119, REPUBLIC OF KOREA

Production of Pulse Oximeters

## Parameters: