SNAS
Reg. No. 305/Q-054

CERTIFICATE

This certifies that the Quality management system for medical devices of company

Bionet Co., Ltd.

5F, 61 Digital-ro 31-gil, Guro-gu, Seoul 08375, Republic of Korea

Manufacturing site: #401, 34, LS-ro 91beon-gil, Dongan-gu, Anyang-si, Gyeonggi-Do 14119, Republic of Korea

has been assessed by 3EC International and found to be in conformance with the following standard:

EN ISO 13485:2016

for the following scope:

DESIGN AND DEVELOPMENT, PRODUCTION, SALE AND DISTRIBUTION OF ACTIVE (NON-IMPLANTABLE) MEDICAL DEVICES:

PATIENT MONITORS, ELECTROCARDIOGRAPHS, SPIROMETERS, FETAL MONITORS, FETAL MONITORING CENTRAL SYSTEM, PATIENT MONITORING CENTRAL SYSTEM AND PULSE OXIMETERS

PRODUCTION AND DISTRIBUTION OF ACTIVE (NON-IMPLANTABLE) MEDICAL DEVICES: HANDHELD ULTRASOUND SCANNERS

Certificate No.: M-0556/23 **Date of issuance: April 2nd, 2024** **Original date of approval: October 20th, 2023**

This certificate is valid from **April 2nd, 2024** to **October 19th, 2026** on condition that organization will maintain effective Quality management system for medical devices. To verify the validity of this certificate please contact our office at: +421 (0)2 5831 8343.

This certificate fully supersedes previous certificate No. M-0556/23 issued on October 20th, 2023.

Issuing office: 3EC International a.s., Hraničná 18, 821 05 Bratislava, Slovak Republic

Dr. Katarína Tomin Srdošová
Head of Certification Body 3EC International a.s.

Certification body 3EC International a.s. is accredited by SNAS under registration number 305/Q-054 with accreditation certificate No. Q-054 for certification of Quality management systems for medical devices covered by EA MLA and IAF MLA.