3EC International a. s., Hraničná 18, 821 05 Bratislava, Slovak Republic
Notified body No. 2265

EU QUALITY MANAGEMENT SYSTEM CERTIFICATE
No. 2025-MDR/QS-017

Bionet Co., Ltd.

Registered place of business: 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 fo Korea
SRN No.: KR-MF-000013439

Name and address of the Authorized representative:
CMC Medical Devices & Drugs SL, C/ Horacio Lengo N18, CP 29006, Málaga, Spain
SRN: ES-AR-000000293

This EU Quality Management System Certificate issued in accordance with the Regulation (EU) 2017/745 of the European Parliament and of the Council on medical devices as amended confirms, that quality management system of medical device:

Fetal Monitoring System
(detailed list is stated in Annex I)
Intended purpose: Annex II
MD class IIb, Rule 10

meets the requirements on quality management system according to the Chapter I and III of Annex IX of the Regulation (EU) 2017/745 of the European Parliament and of the Council on medical devices as amended.

Conditions for or limitations to the validity of the certificate: **N/A**

Validity of the certificate is conditional upon positive results of regular surveillance audits.

Notified body No. 2265 has performed assessment of the quality management system of the abovementioned medical device and found that it meets the requirements stated above. The outcome of the assessment of the quality management system of the abovementioned medical device is stated in the MD Technical Documentation Assessment Report No. MDR347_2023 from 16.11.2024, MD Clinical Evaluation Report No. MDR347_2023 from 16.11.2024 and MD Audit Report No. SK-0700/25 from 21.02.2025. Information on all examinations and tests performed is stated in the abovementioned reports and is available on request.

This **EU Quality Management System Certificate** applies only to the quality management system of the abovementioned medical device. The certificate validity is conditional upon fulfilment of relevant legal requirements by the manufacturer.

Valid from: **28.02.2025**
Valid until: **28.02.2030**
First issue: **28.02.2025**
Revision: **00**
History: **Annex III**

Notified body 3EC international NB 2265 NOTIFIKOVANÁ OSOBA

3EC International a. s.
Katarína Tomin Srdošová, PhD.
Director of NB 2265

In Bratislava, Slovakia, 28.02.2025

ANNEX I TO EU QUALITY MANAGEMENT SYSTEM CERTIFICATE No. 2025-MDR/QS-017

issued for the company

Bionet Co., Ltd.

Registered place of business: 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 fo Korea

List of medical devices covered by the EU Quality Management System Certificate:

Medical device name	Model name	Accessories
Fetal Monitoring System	FC1400	UC Probe, US Probe, Event Marker

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Katarina Tomin Srdošová, PhD.
Director of NB 2265

In Bratislava, Slovakia, 28.02.2025
Valid until 28.02.2030

ANNEX II TO EU QUALITY MANAGEMENT SYSTEM CERTIFICATE No. 2025-MDR/QS-017

issued for the company

Bionet Co., Ltd.

Registered place of business: 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 fo Korea

Intended purpose of medical devices covered by the EU Quality Management System Certificate:

FC1400 detects and displays single or twins Fetal Heart Rate (FHR), Fetal Movement (FM), and Uterine Activity (UA) in real-time, and also provides the fetal heartbeat sound with internal speaker.

Notified body
3EC international
NB 2265
NOTIFIKOVANÁ OSOBA

Katarína Tomin Srdošová, PhD.
Director of NB 2265

In Bratislava, Slovakia, 28.02.2025
Valid until 28.02.2030

ANNEX III TO EU QUALITY MANAGEMENT SYSTEM CERTIFICATE No. 2025-MDR/QS-017

issued for the company

Bionet Co., Ltd.

Registered place of business: 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 fo Korea

Certificate history:

Revision	EU QMS Certificate reference	Date of issue	Application Number for Conformity Assessment	Description
00	2025-MDR/QS-017	28.02.2025	MDR347_2023	Initially granted certification

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Katarína Tomin Srdošová, PhD.
Director of NB 2265

In Bratislava, Slovakia, 28.02.2025
Valid until 28.02.2030