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

EU QUALITY MANAGEMENT SYSTEM CERTIFICATE
No. 2023-MDR/QS-030

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

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:

Handheld Ultrasound Scanners
(detailed list is stated in Annex I)
Intended purpose: Annex II
MD class IIa, 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. MDR083_2022 from 21.06.2023, MD Clinical Evaluation Report No. MDR083_2022 from 21.06.2023 and MD Audit Report No. MDR083_2022 from 15.09.2023. 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: **10.10.2023**
Valid until: **10.10.2028**
First issue: **10.10.2023**
Revision: **00**
History: **Annex III**

In Bratislava, Slovakia, 10.10.2023

Notified body 3EC international NB 2265 NOTIFIKOVANÁ OSOBA

3EC International a.s.
Katarína Tomin Srdošová, PhD.
Director of NB2265