



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 of 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.

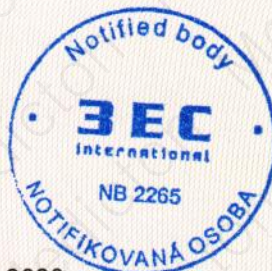
Notified body No. 2265 has performed assessment of the quality management system of the abovementioned medical device and found that it meets the requirements stated above. The outcome of the assessment of the quality management system of the abovementioned medical device is stated in the MD Technical 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



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