

File No.	BN-DOC-US
Rev No.	2
Rev. Date	2023.04.19
Page No.	1 / 1

We, the following manufacturer is sole responsible for this declaration:

Manufacturer	Bionet Co., Ltd.
Address	5F, 61 Digital-ro 31-gil Guro-gu, Seoul 08375, REPUBLIC OF KOREA
European Representative	CMC Medical Devices & Drugs S.L. C/ Horacio Lengo Nº 18, CP 29006, Málaga, Spain
Product Categories	Accessories of Bionet Products
Model Name	US Probe
Catalogue Number	130209-000100, 130201-000600, 130202-000600
GMDN Code & Classification (MDD, Annex IX)	43958 IIa (Rule 10)
Conformity Assessment Route	Annex.II excluding 4

We here with declare that the above-mentioned products meet the provisions of the Council Directive 93/42/EEC amended by MDD 2007/47/EC for medical devices. All supporting documentation is retained under of the manufacture. We are exclusively responsible for the declaration of conformity.

Standards	All applied harmonized Standards were adopted (Published in the Official Journal of the European Communities)
Notified Body	TÜV SÜD Product Service GmbH, Ridlerstr. 65, D-80339 München, Germany



Identification No.:	No.: G1 046135 0044 Rev.00
(EC) CERTIFICATE:	
Issue Date of CE cert.	March 24. 2021
Valid until	May 26. 2024
Place, Date of Declaration	Seoul, April 19, 2023



MINN STEVEN SANGWON, CEO

Name	MINN STEVEN SANGWON
Position	Chief Executive Officer