DECLARATION OF CONFORMITY TO COUNCIL DIRECTIVE 93/42/EEC OF 14 JUNE 1993 CONCERNING MEDICAL DEVICES

Manufacturer Head office	**BIONET Co., Ltd.**
Address	5F, 61 Digital-ro 31-gil Guro-gu, Seoul 08375, REPUBLIC OF KOREA
Manufacturer Facility Address	4F, 34, LS-ro 91beon-gil, Dongan-gu, Anyang-si, Gyeonggi-do, Republic of Korea 14119
European Representative	**CMC Medical Devices & Drugs S.L.** C/ Horacio Lengo Nº 18, CP 29006, Málaga, Spain
Product Categories	ECG Recorder
Model Code &	See Appendix
Classification (MDD, Annex IX)	IIa (Rule 10)
Conformity Assessment Route	Annex.II.3 excluding 4

WE, BIONET, HEREWITH DECLARE THAT THE STATED MEDICAL DEVICES MEET THE TRANSPOSITION INTO NATIONAL LAW, THE PROVISIONS OF COUNCIL DIRECTIVE 93/42/EEC OF 14 JUNE 1993 CONCERNING MEDICAL DEVICES; ALL SUPPORTING DOCUMENTATION IS RETAINED AT THE PREMISES OF THESE MANUFACTURER.
THE MANUFACTURERE IS EXCLUSIVELY RESPONSIBLE FOR THE DECLARARTION OF CONFORMITY

Standards	All applied harmonized Standards were adopted (published in the Official Journal of the European Communities)
Notified Body	POLISH CENTER FOR TESTING AND CERTIFICATION, 469 Puławska Street, 02-844 Warszawa
Identification No.	CE 1434
Certificate No.	1434-MDD-366/2021
Issue Date of CE cert.	May 21. 2021
Valid until	May 27. 2024
Place, Date of Declaration	Seoul, May 24. 2021

Name MINN S. STEVEN

Position Chief Executive Officer

Appendix: List of Devices and Standards applied

No.	Product	Model	Class/ Rule
1	**ECG Recorder**	Cardio7e	IIa, Rule 10

DOC Revision History

BIONET CO., LTD.			Revision
			0
Revision Status	Rev.	Description	Date
	0	Release of DoC including CE marking devices	2021.05.21

Title

Purpose
To demonstrate compliance with ANNEX II, Council Directive 93/42/EEC concerning Medical Devices for the ECG Recorder

Model NO.: Cardio7e

Originator	Reviewed	Confirmed