Connecting Healthcare for Life

bionet

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	#903, Shinil IT uto, 13, LS-ro, Gunpo-Si, Gyeonggi-Do 15843, REPUBLIC OF KOREA
European Representative	**MGB Endoskopische Geräte GmbH Berlin** Schwarzschildstr. 6, 12489 Berlin, GERMANY
Product Categories	ECG Recorders, Fetal Monitors, Patient Monitors,
Model Code &	*See Appendix*
Classification (MDD, Annex IX)	IIa, IIb(Rule 10, 11)
Conformity Assessment Route	Annex.II.3 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.	CE 0123
Certificate No.	G1 046135 0045 Rev.00
Issue Date of CE cert.	2020-04-02
Valid until	2024-05-26
Place, Date of Declaration	Seoul, 2020-06-11

Name MINN Steven Sangwon

Position Chief Executive Officer

Appendix : List of Devices and Standards applied

No.	Product	Model	Class/ Rule
1	**ECG Recorder**	CardioCare 2000	IIa, Rule 10
2	**Fetal Monitors**	FC 700	IIb, Rule 10
3		FC 1400	
4	**Patient Monitors**	BM3	IIb, Rule 10
5		BM5	

DOC Revision record

Bionet Co.,Ltd			**Revision**
			0
Revision Status	**Rev.**	**Description**	**Date**
	0	Release of DoC for GIMA including CE marking devices	2020-06-11

Title

Purpose
To demonstrate compliance with ANNEX Ⅱ, Council Directive 93/42/EEC concerning Medical Devices for the ECG Recorders, Fetal Monitors and Patient Monitors.

Model NO.: CardioCare2000, FC 700, FC 1400, BM3, BM5.

Originator	**Reviewed**	**Confirmed**