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	CMC Medical Devices & Drugs S.L.: Horacio Legno N° 18, CP 29006, Malaga, SPAIN
Product Categories	ECG Recorders, Fetal Monitors, Patient Monitors, Fetal Monitoring Central System, Patient Monitoring Central System, Pulse Oximeters
Model Code &	*See Appendix*
Classification (MDD, Annex IX)	IIa, IIb (Rule 10, 11)
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.	CE 0123
Certificate No.	G1 046135 0044 Rev.00
Issue Date of CE cert.	**March** 24. 2021
Valid until	May 26. 2024
Place, Date of Declaration	March 29. 2021, Seoul

Name	MINN STEVEN SANGWON
Position	Chief Executive Officer

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Appendix : List of Devices and Standards applied

No.	Product	Model	Class/ Rule
1	**ECG Recorder**	CardioCare2000	IIa, Rule 10
2		CardioTouch3000	
3		Care Vision 512i	
4	**Fetal Monitors**	FC700	IIb, Rule 10
5		FC1400	
6		FetalXP	
7		UC Probe	IIa, Rule 10
8	**Fetal Monitoring Central System**	FC Central	IIb, Rule 10
9	**Patient Monitors**	BM1	IIb, Rule 10
10		BM3	
11		BM5	
12		BM7	
13	**Patient Monitoring Central System**	BM Central	
14	**Pulse Oximeters**	Oxy9Wave	IIb, Rule 10

DOC Revision record

Bionet Co.,Ltd			Revision 14
Revision Status	Rev.	Description	Date
	0	Release of DoC including all CE marking devices	2010-07-15
	1	Revision -Add the MU1, BM7 -Change of address notation -The certificate number & issue date of EC Certificate	2012-09-28
	2	Revision -The certificate number & issue date of EC Certificate	2013-04-12
	3	Revision -The certificate number & issue date of EC Certificate -Add the address of facility -Delete the Zertifizierstelle. -Delete the Pulse oximeters.	2015-09-09
	4	Revision - Add the Oxy9wave - Change of postal cord -The certificate number & issue date of EC Certificate	2015-11
	5	Revision -Delete the Babycare -Add the Care Vision 512i - the registration number of EC Certificate	2017-01
	6	Revision -Change class of FC 700, FC 1400 to class IIb	2017-05
	7	Revision -Change addresses of Head office and Facility	2017-09
	8	Revision -Delete of Standards applied in Appendix -Issue of new certificates	2018-01
	9	Revision -Add the CH-100, delete MU1 -Change the originator and Reviewer	2019-03
	10	Revision -Change the Confirmed	2019-06
	11	Revision -Delete the product PION TCI, PION Syringe Pump, PION Neo Syringe, CardioTouch3000S, Cardio7, Cardio XP.	2019-10-01
	12	Revision -Change the Confirmed	2020-03-18
	13	Revision - Update certificate number and valid date	2020-04-28
	14	Revision - Update certificate number and replace EC Representative	2021-03-29

Title

Purpose

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

Model NO.: CardioCare2000, CardioTouch3000, Care Vision 512i, CH-100, FC 700, FC 1400, FC Central, Fetal XP, UC Probe, BM1, BM3, BM3 Plus, BM3 Wide, BM3 Lite, BM5, BM5 CS, BM5 CX, BM Central, BM7, Oxy9wave

Originator	Reviewed	Confirmed