

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

<b>Manufacturer Head office Address</b>	<b>Bionet Co., Ltd.</b> 5F, 61 Digital-ro 31-gil Guro-gu, Seoul 08375, REPUBLIC OF KOREA
<b>Manufacturer Facility Address</b>	#903, Shinil IT uto, 13, LS-ro, Gunpo-Si, Gyeonggi-Do 15843, REPUBLIC OF KOREA
<b>European Representative</b>	CMC Medical Devices & Drugs S.L.: Horacio Legno N° 18, CP 29006, Malaga, SPAIN
<b>Product Categories</b>	ECG Recorders, Fetal Monitors, Patient Monitors, Fetal Monitoring Central System, Patient Monitoring Central System, Pulse Oximeters
<b>Model Code &amp; Classification (MDD, Annex IX) Conformity Assessment Route</b>	<i>See Appendix</i> IIa, IIb (Rule 10, 11) 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.*

<b>Standards</b>	All applied harmonized Standards were adopted (published in the Official Journal of the European Communities)
<b>Notified Body</b>	TÜV SÜD Product Service GmbH, Ridlerstr. 65, D-80339 München, Germany
<b>Identification No.</b>	
<b>Certificate No.</b>	G1 046135 0044 Rev.00
<b>Issue Date of CE cert.</b>	<b>March 24. 2021</b>
<b>Valid until</b>	May 26. 2024
<b>Place, Date of Declaration</b>	March 29. 2021, Seoul

<b>Name</b>	 _____
<b>Position</b>	MINN STEVEN SANGWON Chief Executive Officer

**Appendix : List of Devices and Standards applied**

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

# bionet 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	
<b>Title</b>			
<b>Purpose</b> 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.			
<b>Model NO.:</b> 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			
<b>Originator</b>		<b>Reviewed</b>	<b>Confirmed</b>

