Document Rev. 11

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

Manufacturer	**Bionet Co., Ltd.**
Address	#1101 11F, E&C Venture Dream Tower 3 38-21, Digital-Ro 31-Gil, Guro-Gu, Seoul 152-719, Republic of Korea
European Representative	**MGB Endoskopische Geräte GmbH Berlin** Schwarzschildstr. 6 12489 Berlin, Germany
Product	Patient Monitors, Patient Monitoring Central System
Model Code	BM1, BM3, BM3 Plus, BM5, BM7, BMCentral
Serial Number	BM1[DBN1000001], BM3[D1O0100001] BM5[D8O0300001], BM7[DEO0100001] BM3Plus[D3N1200001]
Classification (MDD, Annex IX)	IIb, 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 THE MANUFACTURER. RELEVANT EC DIRECTIVES: MEDICAL DEVICE DIRECTIVE 93/42/EEC AS AMENDED BY DIRECTIVE 2007/47/EC

Standard

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 15 04 46135 034
Issue Date of CE cert.	2015-06-27
Valid until	2020-06-26
Place, Date of Declaration	Seoul, 2015-07-02

Digitally signed by Graba
Date: 2019.03.05 14:19:29
Reason: MoldSign Signatu
Location: Moldova

Name	Dong Joo, Kang
Position	Chief Executive Officer

DOC Revision record

Bionet Co., Ltd			Revision
			11
Revision Status	Rev.	Description	Date
	0	Release of the technical file for BM3, BM3 Plus	2003-01
	1	Revision - Adding model of the BM5	2005-09
	2	Revision - Add the BMCentral PC Software - Change of BM3 LCD Display ■ 5.7inch STN → 7inch TFT	2008-06
	3	Revision - the registration number & date of EC Certificate	2008-11
	4	Revision - the registration number & date of EC Certificate - Adding model of the BM1	2010-01-01
	5	Revision - Add the issue date of DoC	2010-04-20
	6	Revision - the registration number of EC Certificate	2010-06-14
	7	Revision - the registration number & issue date of EC Certificate	2010-08-25
	8	Revision - change of address notation	2012-04-01
	9	Revision - Adding model of the BM7	2012-09-05
	10	Revision -Change of Conformity Assessment Route - Annex.II.3 to Annex.II.3 excluding 4 -Change for address of Notified Body - Delete of Zertifizierstelle	2014-09-02
	11	Revision -change of Certificate No. , Issue Date of CE cert, Valid until and Place; Date of Declaration	2015-07-02

Title

Purpose

To demonstrate compliance with ANNEX Ⅱ, Council Directive 93/42/EEC concerning Medical Devices for the BM1, BM3, BM3 Plus, BM5, BM7 Patient Monitors & S/W BMCentral

Model NO.: BM1, BM3, BM3 Plus, BM5, BM7, BMCentral		
Originator	**Reviewed**	**Confirmed**

Document Rev. 9

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

Manufacturer	**Bionet Co., Ltd.**
Address	#1101 11F, E&C Venture Dream Tower 3 38-21, Digital-Ro 31-Gil, Guro-Gu, Seoul 152-719, Republic of Korea
European Representative	**MGB Endoskopische Geräte GmbH Berlin** Schwarzschildstr. 6 12489 Berlin, Germany
Product	ECG Recorders, Spirometers
Model Code	CardioCare-2000(EKG-2000), CardioTouch-3000, (EKG-3000), CardioTouch-3000S(EKG-3000S) CardioXP, Cardio 7
Serial Number	CardioCare-2000[EO0100001], CardioXP[XO0100001] CardioTouch-3000[T2O0100001], Cardio7[T7O0100001]
Classification (MDD, Annex IX)	IIa, Rule 10
Conformity Assessment Route	Annex.II.3 excluding 4

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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 THE MANUFACTURER. RELEVANT EC DIRECTIVES: MEDICAL DEVICE DIRECTIVE 93/42/EEC AS AMENDED BY DIRECTIVE 2007/47/EC

Standard

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 15 04 46135 034
Issue Date of CE cert.	2015-06-27
Valid until	2020-06-26
Place, Date of Declaration	Seoul,2015-07-02

Name Dong Joo, Kang

Position Chief Executive Officer

DOC Revision record

Bionet Co.,Ltd			Revision
			9
Revision Status	Rev.	Description	Date
	0	Release of the technical file for EKG2000,EKG3000	2002-01
	1	Release of the technical file for CardioXP	2008-08-20
	2	Revision - the registration number & date of EC Certificate	2008-11
	3	Revision - the registration number & date of EC Certificate	2009-10-23
	4	Revision -Add the issue date of DoC	2010-04-20
	5	Revision - the registration number & date of EC Certificate	2010-06-14
	6	Revision - the registration number & issue date of EC Certificate	2010-08-25
	7	Revision - change of address notation	2012-04-01
	8	Revision -Change of Conformity Assessment Route - Annex.II.3 to Annex.II.3 excluding 4 -Change for address of Notified Body - Delete of Zertifizierstelle	2014-09-02
	9	Revision -change of Certificate No. , Issue Date of CE cert, Valid until and Place; Date of Declaration	2015-07-02

Title

Purpose

To demonstrate compliance with ANNEX Ⅱ, Council Directive 93/42/EEC concerning Medical Devices for the ECG Recorders, Spirometers.

Bionet

Model NO.: CardioCare2000, CardioTouch3000, CardioTouch3000S, CardioXP		
Originator	**Reviewed**	**Confirmed**

Document Rev. 4

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

Manufacturer	**Bionet Co., Ltd.**
Address	#1101 11F, E&C Venture Dream Tower 3 38-21, Digital-Ro 31-Gil, Guro-Gu, Seoul 152-719, Republic of Korea
European Representative	**MGB Endoskopische Geräte GmbH Berlin** Schwarzschildstr. 6 12489 Berlin, Germany
Product	Fetal Monitor, Fetal Monitoring Central System
Model Code	Fetal XP, FC Central
Serial Number	Fetal XP[F4O0100001]
Classification (MDD, Annex IX)	IIb, 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 THE MANUFACTURER. RELEVANT EC DIRECTIVES: MEDICAL DEVICE DIRECTIVE 93/42/EEC AS AMENDED BY DIRECTIVE 2007/47/EC

Standard

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 15 04 46135 034
Issue Date of CE cert.	2016-06-27
Valid until	2020-06-26
Place, Date of Declaration	Seoul, 2015-07-02

Name Dong Joo, Kang

Position Chief Executive Officer

DOC Revision record

Bionet Co.,Ltd			Revision
			4
Revision Status	Rev.	Description	Date
	0	Release of the technical file for FetalXP	2010-12
	1	Revision - change of address notation	2012-04
	2	Revision - the registration number & date of EC Certificate	2013-04
	3	Revision -Change of Conformity Assessment Route - Annex.II.3 to Annex.II.3 excluding 4 -Change for address of Notified Body - Delete of Zertifizierstelle	2014-09
	4	Revision -change of Certificate No. , Issue Date of CE cert, Valid until and Place; Date of Declaration -Add the FC Central PC Software	2015-07-02

Title

Purpose

To demonstrate compliance with ANNEX Ⅱ, Council Directive 93/42/EEC concerning Medical Devices for FetalXP Fetal Monitors & S/W FC Central.

Model NO.: FetalXP

Originator	Reviewed	Confirmed

Document Rev. 11

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

Manufacturer	**Bionet Co., Ltd.**
Address	#1101 11F, E&C Venture Dream Tower 3 38-21, Digital-Ro 31-Gil, Guro-Gu, Seoul 152-719, Republic of Korea
European Representative	**MGB Endoskopische Geräte GmbH Berlin** Schwarzschildstr. 6 12489 Berlin, Germany
Product	Fetal Monitor, Fetal Monitoring Central System
Model Code	FC700, FC1400, FC Central
Serial Number	FC700[FO0100001],FC1400[F2O0100001]
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 THE MANUFACTURER. RELEVANT EC DIRECTIVES: MEDICAL DEVICE DIRECTIVE 93/42/EEC AS AMENDED BY DIRECTIVE 2007/47/EC

Standard

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 15 04 46135 034
Issue Date of CE cert.	2015-06-27
Valid until	2020-06-26
Place, Date of Declaration	Seoul, 2015-07-02

Name	Dong Joo, Kang
Position	Chief Executive Officer

DOC Revision record

Bionet Co.,Ltd			Revision
			11
Revision Status	Rev.	Description	Date
	0	Release of the technical file for FC700, FC1400	2003-01
	1	Revision - Add the FC Central PC Software	2008-06
	2	Revision - the registration number & date of EC Certificate	2008-11
	3	Revision - the registration number & date of EC Certificate	2009-10-23
	4	Revision -Add the issue date of DoC	2010-04-20
	5	Revision - the registration number & date of EC Certificate	2010-06-14
	6	Revision - the registration number & issue date of EC Certificate	2010-08-25
	7	Release of the technical file for Fetal XP	2010-12-13
	8	Revision - change of address notation	2012-04-01
	9	Revision - the registration number & date of EC Certificate	2013-04-16
	10	Revision -Change of Conformity Assessment Route - Annex.II.3 to Annex.II.3 excluding 4 -Change for address of Notified Body - Delete of Zertifizierstelle	2014-09-02
	11	Revision -change of Certificate No. , Issue Date of CE cert, Valid until and Place; Date of Declaration - Delete of Fetal XP	2015-07-02

Title

Purpose

To demonstrate compliance with ANNEX Ⅱ, Council Directive 93/42/EEC concerning Medical Devices for the FC700, FC1400 Fetal Monitors & S/W FC Central

Model NO.: FC700, FC1400, FC Central		
Originator	Reviewed	Confirmed