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

Manufacturer	**Bionet Co., Ltd.**
Address	5F, Shinsegae I&C Digital Center 61 Digital-ro 31 gil, Guro-gu, SEOUL 08375, 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, BM5, BM7, BM Central
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.
A statement that the manufacturer is exclusively responsible for the declaration of conformity.
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 17 11 46135 041
Issue Date of CE cert.	2018-01-23
Valid until	2020-06-26
Place, Date of Declaration	Seoul, 2018-01-24

Name	Dong Joo, Kang
Position	Chief Executive Officer

DOC Revision record

Bionet Co., Ltd			Revision
			15
	Rev.	**Description**	**Date**
Revision Status	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
	12	Revision -Delete of BM3 Plus	2015-07-14
	13	Revision - Change of Certificate No. Issue Date of CE cert. - Revise the postal code	2015-11-27
	14	Revision - insert the content that manufacturer is responsible for the DoC	2016-11-24
	15	Revision - the registration number of EC Certificate - Change of manufacturer's address	2017-01-03
	16	Revision - Change of Certificate No. Issue Date of CE cert.	2018-01-24

Title

Purpose

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

Model NO.: BM1, BM3, BM5, BM7, BM Central

Originator	Reviewed	Confirmed