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

Manufacturer Head office	**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	ECG Recorder, ECG Recorder & Spirometer, Spirometers
Model Code	EKG 2000, Cardio 7, SPM-300
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.
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
			14
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
	10	Revision - The registration number & date of EC Certificate -Revise the postal code	2015-12-08
	11	Revision - Added the product of DoC; Carevision 512i and SPM-300	2016-05-10
	12	Revision - insert the content that manufacturer is responsible for the DoC	2016-11-24
	13	Revision - the registration number of EC Certificate	2017-01-03
	14	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 ECG Recorder, ECG Recorder & Spirometer, Spirometers		
Model NO.: EKG 2000, Cardio 7, SPM-300		
Originator	**Reviewed**	**Confirmed**