



EC Certificate Full Quality Assurance System: Certificate KR19/81826300

The management system of

Bionics Co., Ltd.

Suite 103, 201 Gangwon Techno Park Chuncheon Venture 2nd Factory,
Sinbuk-ro 61-14, Sinbuk-eup, Chuncheon-si, Gangwon-do, Republic of Korea

has been assessed and certified as meeting the requirements of

Directive 93/42/EEC on medical devices, Annex II (excluding Section 4)

For the following products

- Patient monitor for vital physiological parameters
(Model : PalmCare plus, BPM-190, BPM-1010 and BPM-1200);
- Fetal monitor for monitoring fetus heart rate and the uterus shrinkage
(Model: BFM-900, BFM-900L);
- Electrocardiograph for detecting and measuring of Pulse rate
and multi channel ECG (Model: BCM-300, BCM-600)

Where the above scope includes class III medical device(s), a valid EC Design Examination Certificate according to Annex II (Section 4) is a mandatory requirement for each device in addition to this certificate to place that device on the market.

This certificate is valid from 16 December 2020 until 18 March 2024
and remains valid subject to satisfactory surveillance audits.
Issue 3. Certified since 18 March 2010
and first certified by SGS Belgium NV since 16 February 2020

Certification is based on reports numbered KR/SEL Y-PC/09221

Authorised by

SGS Belgium NV, Notified Body 1639

SGS House Noorderlaan 87 2030 Antwerp Belgium
t +32 (0)3 545-48-48 f +32 (0)3 545-48-49 www.sgs.com

LPMD5007 - Certificate CE1639 Annex II-4_EN rev. 02

Page 1 of 1



GIÁM ĐỐC
Nguyễn Hồng Nga



This document is issued by the Company subject to its General Conditions of Certification Services, unless otherwise agreed, accessible at www.sgs.com/terms_and_conditions.htm. Attention is drawn to the limitations of liability, indemnification and jurisdictional issues established therein. The authenticity of this document may be verified at <https://www.sgs.com/en/certified-clients-and-products/certified-client-directory>. Any unauthorized alteration, forgery or falsification of the content or appearance of this document is unlawful and offenders may be prosecuted to the fullest extent of the law.