



National Institute of Medical Device Safety Information

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Tel: +82-2-860-4450, Fax: +82-2-860-4479

Certificate of Free Sales

No. of Certificate : 20220039461
Exporting(certifying) country : Republic of Korea
Importing(requesting) country :

The National Institute of Medical Device Safety Information, certifies that the following firm is authorized to manufacture medical devices under the Medical Device Act, and the following product(s) is(are) permitted to be freely sold in domestic and overseas markets.

○ Applicant (=Product-license holder)

(This certificate shall not be issued to others than the product-license holder)

- Name : Bionics Co.,Ltd.

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

- Registered No : Manufacturer 1936

No. and date of product-license, comments	Classification
06-184 / MAR. 13. 2006	Electrocardiograph [2]
07-258 / MAY. 09. 2007	Perinatal monitoring system [2]
11-221 / MAR. 07. 2011	Electrocardiographic analyser [2]
11-38 / JAN. 12. 2011	Pulse oximeter, line-powered [2]
13-1186 / JUL. 05. 2013	Patient monitor [2]

※ Attached, if necessary (approved product information)

- Model(Export Name)
 Medical Device Accessories
 Manufacturer/Legal manufacturer
 Combined/Composite medical device



Issued date : APR. 14. 2022 (Certificate No.20220039461)

Certified by

이성희

Director of Medical Device Certification Department
National Institute of Medical Device Safety Information

The National Institute of Medical Device Safety Information(NIDS) is related organization of Ministry of Food and Drug Safety and established under Article 42 of the Medical Device Act.
The Minister of Food and Drug Safety authorized the director of NIDS to issue this free sales certificate under the Article 44 (2) of the Medical device Act.

Attachment

Product License No. : 06-184 (AUG. 10. 2016)

Classification : Electrocardiograph

Model(Export Name)

· BCM-300

Product License No. : 07-258 (AUG. 10. 2016)

Classification : Perinatal monitoring system

Model(Export Name)

· BFM-900

Product License No. : 11-221 (AUG. 10. 2016)

Classification : Electrocardiographic analyser

Model(Export Name)

· BCM-600

Product License No. : 11-38 (FEB. 10. 2022)

Classification : Pulse oximeter, line-powered

Model(Export Name)

· PalmCare plus

Product License No. : 13-1186 (AUG. 10. 2016)

Classification : Patient monitor

Model(Export Name)

- BPM-1200	- BPM-1010
- BPM-190	

Certificate of Authentication

Seen at the Ministry of Foreign Affairs of the Republic of Korea.
Valid only if submitted to foreign missions in the Republic of Korea.

1. Country : Republic of Korea



Certified

To verify the Certificate, please refer to the website below.
<https://www.apostille.go.kr>

2. at Seoul 3. the 19/04/2022

4. by The Ministry of Foreign Affairs

5. No. XXC2022F52F3YN

6. Seal/stamp

7. Signature

Park Kwan Seok



ĐẠI SỨ QUÁN NƯỚC CHXHCN VIỆT NAM TẠI HÀN QUỐC
THE EMBASSY OF THE SOCIALIST REPUBLIC OF VIETNAM IN THE REPUBLIC OF KOREA

CHỨNG NHẬN / HỢP PHÁP HÓA LÃNH SỰ CONSULAR AUTHENTICATION

1. Quốc gia Việt Nam
Country Vietnam

Giấy tờ, tài liệu này
This public document

2. do Ông (Bà) Park Kwan Seok ký
has been signed by

3. với chức danh Viên chức lãnh sự
acting in the capacity of

4. và con dấu của Bộ Ngoại giao Hàn Quốc
bears the seal/stamp of
Ministry of Foreign Affairs
of the Republic of Korea

được chứng nhận / hợp pháp hóa lãnh sự
Certified

5. tại Hàn Quốc 6. ngày 20.04.2022...
at The Republic of Korea on

7. Cơ quan cấp Đại sứ quán nước CHXHCN Việt Nam tại Hàn Quốc
by The embassy of the S.R. of Vietnam in the Republic of Korea

8. Số 013504
No CNLS/HPHLS
Ký tên và đóng dấu
Signature and seal/stamp

Tham tán Công sứ / Minister Counsellor



Trần Trường Thủy

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