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EC CERTIFICATION

FULL QUALITY ASSURANCE SYSTEM

Directive 93/42/EEC on Medical Devices, Annex II excluding (4)

We hereby declare that an examination of the under mentioned full quality assurance system has been carried out following the requirements of the Swedish national legislation LVFS 2003:11 to which the undersigned is subjected, transposing Annex II (with the exemption of section 4) of the Directive 93/42/EEC on medical devices. We certify that the full quality assurance system conforms with the relevant provisions of the aforementioned directive, and the result entitles the organization to use the CE 0413 marking on those products listed below.

Certificate Number:
41316438-03

Initial Certification Date:
14 July 2008

Certificate Valid from:
28 April 2021

Certificate Expiry Date:
14 July 2023

SWEDAC ACKREDITERING
Accred. no. 1003
Certification of Management Systems
ISO/IEC 17021-1

Organization:

Shenzhen Pango Medical Electronics Co., Ltd

Main Site: No.25 1st Industry Zone, Fenghuang Rd, Xikeng Village, Henggang Town, Longgang District, Shenzhen City, Guangdong Province, China

Product Category:

- Electronic Blood Pressure Monitors
- Nerve and muscle stimulators

For further identification of the products covered, see the MDD product list/product schedule.

Peter Nermander
Certification Authority MDD
Intertek Semko AB, Kista, Sweden

28 April 2021
Signed Date

Intertek Semko AB
Box 1103, SE-164 22 Kista, Sweden
Telephone +46 8 750 00 00
medtechsweden@intertek.com

The certification is subject to the organization maintaining their system in compliance with the regulations stated in this certificate, allowing regular assessments and following the contracted requirements of the Notified Body.

Intertek Semko AB is a Notified Body according to Directive 93/42/EEC on medical devices, with identification number 0413.

MDD – Decision Report

Certificate No: 41316438-03
Date: 28 April 2021
Handled by: Caroline Åman
E-mail: medtechsweden@intertek.com

Shenzhen Pango Medical Electronics Co., Ltd
Attn: 黄 正华
No.25 1st Industry Zone, Fenghuang Rd,
Xikeng Village, Henggang Town,
Longgang District, Shenzhen City,
Guangdong Province, China

Purpose	Assessment to issue a new EC certificate due to name change. Manufacturer has change name from *Shenzhen Pango Electronic Co., Ltd* (adding *Medical*). Decision was made according to the national legislation for medical devices LVFS 2003:11 (Medical Device Directive 93/42/EEC), Annex II.
Scope of assessment	- Electronic Blood Pressure Monitors - Nerve and muscle stimulators Class IIa
Result	The name change has been accepted. Updated EC Certificate and Product List will be issued to reflect the name change.
Certificate Valid from	28 April 2021
Conclusions/Decisions	Referring to the above a Certificate of Conformance with the national legislation for medical devices LVFS 2003:11 (Medical Device Directive 93/42/EEC), Annex II will be issued. The Certificate is valid for products specified in the "MDD – Product List".
Follow-up assessments	Follow-up assessments are going to be performed once a year.
Appeals	Any appeal against this decision will be processed by an appeals panel as Intertek. The appeal shall be submitted to Intertek Semko AB, PO-Box 1103, SE-164 22 Kista, Sweden.
Others	Any complaints, from customers and others, and corrective actions concerning your certified quality system shall be documented and retained. Upon request Intertek Semko has the right to review this documentation.

Intertek Semko AB
Notified Body MDD

Peter Nermander
Certification Authority MDD

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MDD – Product List

Products included in the Certificate No: 41316438-03
Issued to: **Shenzhen Pango Medical Electronics Co., Ltd**
No.25 1st Industry Zone, Fenghuang Rd, Xikeng Village, Henggang Town, Longgang District, Shenzhen City, Guangdong Province, China

Product category	Type/Model designation	Class	Sterile	GMDN code (not mandatory)	Date added
Electronic Blood Pressure Monitor					
	PG-800A	IIa	No	-	*
	PG-800B	IIa	No	-	*
	PG-800AD	IIa	No	-	Nov 17, 2011
	PG800A-1	IIa	No	-	Nov 17, 2011
	PG800AD-1	IIa	No	-	Nov 17, 2011
	PG-800A3	IIa	No	-	Nov 17, 2011
	PG-800A4	IIa	No	-	Nov 17, 2011
	PG-800A4D	IIa	No	-	Nov 17, 2011
	PG-800A5	IIa	No	-	Nov 17, 2011
	PG-800A5D	IIa	No	-	Nov 17, 2011
	PG-800A6	IIa	No	-	Nov 17, 2011
	PG-800A6D	IIa	No	-	Nov 17, 2011
	PG-800A7	IIa	No	-	Nov 17, 2011
	PG-800A7D	IIa	No	-	Nov 17, 2011
	PG-800A6-1	IIa	No	-	Nov 17, 2011
	PG-800A8	IIa	No	-	Jan 31, 2013
	PG-800A9	IIa	No	-	Nov 17, 2011
	PG-800A11	IIa	No	-	Jan 31, 2013
	PG-800A11-1	IIa	No	45617	April 04, 2019
	PG-800A12	IIa	No	-	Jan 31, 2013
	PG-800A15	IIa	No	-	Jan 31, 2013
	PG-800A16	IIa	No	-	Jan 31, 2013
	PG-800A18	IIa	No	45617	April 04, 2019
	PG-800A19	IIa	No	45617	April 04, 2019
	PG-800A25	IIa	No	-	June 5, 2014
	PG-800A27	IIa	No	-	June 5, 2014
	PG-800A28	IIa	No	45617	April 04, 2019
	PG-800A31	IIa	No	-	June 5, 2014
	PG-800A32	IIa	No	-	June 5, 2014
	PG-800A33	IIa	No	-	June 5, 2014
	PG-800A35	IIa	No	-	June 5, 2014
	PG-800A36	IIa	No	-	June 5, 2014
	PG-800A36-1	IIa	No	45617	April 04, 2019
	PG-800A37	IIa	No		June 5, 2014
	PG-800A37-1	IIa	No	45617	April 04, 2019
	PG-800A51	IIa	No	45617	April 04, 2019
	PG-800A52	IIa	No	45617	April 04, 2019
	PG-800BD	IIa	No	-	Nov 17, 2011

Intertek Semko AB
Torshamnsgatan 43, Box 1103, SE-164 22 Kista, Sweden
Telephone +46 8 750 00 00, Fax +46 8 750 60 30, www.sweden.intertek-etlsemko.com
Registered in Sweden: No SE556024059901, Registered office: As address

MDD – Product List

Product category	Type/Model designation	Class	Sterile	GMDN code (not mandatory)	Date added
	PG-800B-1	IIa	No	-	Nov 17, 2011
	PG-800BD-1	IIa	No	-	Nov 17, 2011
	PG-800B3	IIa	No	-	Nov 17, 2011
	PG-800B4	IIa	No	-	Nov 17, 2011
	PG-800B4D	IIa	No	-	Nov 17, 2011
	PG-800B5	IIa	No	-	Nov 17, 2011
	PG-800B5-1	IIa	No	-	Nov 17, 2011
	PG-800B6	IIa	No	-	Nov 17, 2011
	PG-800B6D	IIa	No	-	Nov 17, 2011
	PG-800B6-1	IIa	No	-	Nov 17, 2011
	PG-800B8	IIa	No	-	Jan 31, 2013
	PG-800B9	IIa	No	-	Nov 17, 2011
	PG-800B10	IIa	No	-	Jan 31, 2013
	PG-800B11	IIa	No	-	Jan 31, 2013
	PG-800B12	IIa	No	-	Jan 31, 2013
	PG-800B15	IIa	No	-	Jan 31, 2013
	PG-800B16	IIa	No	-	Jan 31, 2013
	PG-800B18	IIa	No	45617	April 04, 2019
	PG-800B19	IIa	No	45617	April 04, 2019
	PG-800B19L	IIa	No	45617	April 04, 2019
	PG-800B22	IIa	No	-	June 5, 2014
	PG-800B23	IIa	No	-	June 5, 2014
	PG-800B25	IIa	No	-	Jan 31, 2013
	PG-800B26	IIa	No	-	June 5, 2014
	PG-800B27	IIa	No	-	June 5, 2014
	PG-800B28	IIa	No	45617	April 04, 2019
	PG-800B29	IIa	No	45617	April 04, 2019
	PG-800B31	IIa	No	-	June 5, 2014
	PG-800B32	IIa	No	-	June 5, 2014
	PG-800B33	IIa	No	-	June 5, 2014
	PG-800B35	IIa	No	-	June 5, 2014
	PG-800B36	IIa	No	-	June 5, 2014
	PG-800B37	IIa	No	-	June 5, 2014
	PG-800B41	IIa	No	-	Feb 19, 2016
	PG-800B42	IIa	No		Feb 19, 2016
	PG-800B43	IIa	No		Feb 19, 2016
	PG-800B51	IIa	No	45617	April 04, 2019
	PG-800B68	IIa	No	-	June 5, 2014
	PG-800B69	IIa	No	-	June 5, 2014
	JC-601	IIa	No	-	May 4, 2015
	PG-800B45	IIa	No	45617	Dec 15, 2020
	PG-800B46	IIa	No	45617	Dec 15, 2020
	PG-800B47	IIa	No	45617	Dec 15, 2020

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MDD – Product List

Product category	Type/Model designation	Class	Sterile	GMDN code (not mandatory)	Date added
Nerve and muscle stimulators					
	PG-2601B7	IIa	No	-	August 28, 2017
	PG-2601B6	IIa	No	-	August 28, 2017
	PG-2601B8	IIa	No	-	August 28, 2017
	PG-2601B9	IIa	No	-	August 28, 2017
	PG-2601B21	IIa	No	-	August 28, 2017
	PG-2601B22	IIa	No	-	August 28, 2017
	P6	IIa	No	-	Dec 15, 2020
	P7	IIa	No	-	Dec 15, 2020

* Product added before November 17, 2011.

Valid Date: 28 April 2021

Intertek Semko AB
Notified Body MDD

Peter Nermander
Certification Authority MDD

This product list is only valid together with the referenced, valid EC certificate.

The GMDN codes are assigned by the manufacturer and are only provided for convenience.

Intertek Semko AB is a Notified Body according to the Directive 93/42/EEC on medical devices, with identification number 0413.

Intertek Semko AB
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