Shenzhen Pango Medical Electronics Co., Ltd
深圳攀高医疗电子有限公司

Main site: No. 25, 1st Industrial Zone, Fenghuang Road, Xikeng Village, Henggang Town, Longgang District, Shenzhen 518115, Guangdong, P.R.
China
中国广东省深圳市龙岗区横岗街道西坑一村工业区凤凰路25号1号厂房
2023 July 06

Notified Body Confirmation Letter
Reference: 41316438-03 - CN00368-01

To whom it may concern,

Confirmation of the status of a formal application, written agreement, and appropriate surveillance in the framework of Regulation EU 2023/607 amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices

This letter confirms that, Intertek Medical Notified Body AB, a Notified Body (NB) designated against Regulation (EU) 2017/745 (MDR) and identified by the number 2862 on NANDO, has received a formal application in accordance with Section 4.3, first subparagraph of Annex VII of MDR and has signed a written agreement in accordance with Section 4.3, second subparagraph of Annex VII of MDR with the following manufacturer:

Shenzhen Pango Medical Electronics Co., Ltd
No. 25, 1st Industrial Zone, Fenghuang Road
Xikeng Village, Henggang Town, Longgang District, Shenzhen 518115, Guangdong
P.R. China
SRN Number: CN-MF-000023018

The devices covered by the formal application and the written agreement mentioned above are identified in the Tables below. Table 1 identifies the devices for which an MDR application has been received, written agreement concluded and for which the NB is also responsible for appropriate surveillance of the corresponding devices under the applicable Directive. Table 2 identifies the devices for which an MDR application has been received and a written agreement concluded, but the NB has not yet taken the responsibility for appropriate surveillance of the corresponding devices under the applicable Directive.

In the case of devices covered by certificates issued under Directive 90/385/EEC (AIMDD) or Directive 93/42/EEC (MDD) that expired after 26 May 2021 and before 20 March 2023, without having been withdrawn, this letter also confirms that the manufacturer signed the written agreement under MDR by the date of MDD/AIMDD certificate expiry; or provided evidence that a competent authority of a Member State had granted a derogation or exemption from the applicable conformity assessment procedure in accordance with Article 59(1) of MDR or Article 97(1) of the MDR respectively, by the 20 Mar 2023 for the relevant devices.

The transition timelines that apply to the devices covered by this letter, subject to the manufacturer's continued compliance to the other conditions specified in Article 120.3c of MDR (as amended by (EU) 2023/607), are shown below:

- 26 May 2026 for Class III custom-made implantable devices
- 31 December 2027 for Class III devices and Class IIb implantable devices excluding Well-established technologies (WET - sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips and connectors)
- 31 December 2028 for other Class IIb devices, Class IIa, Class I devices placed on the market in sterile condition or have a measuring function
- 31 December 2028 for devices not requiring the involvement of a notified body under MDD but requiring it under MDR (e.g., class I devices that qualify as re-usable surgical instruments)

On behalf of the Notified Body,

Brian Mather
Certification Manager
Intertek Medical Notified Body AB

Table 1: Devices covered by this letter and for which the NB is also responsible for appropriate surveillance of the corresponding devices under the applicable Directive:

Ref Number/ Device Identification	Device Name	Device classification	MDD Certificate Reference(s)
PG-800B	Electronic Blood Pressure Monitor	IIa	41316438-03
PG-800BD	Electronic Blood Pressure Monitor	IIa	41316438-03
PG-800B-1	Electronic Blood Pressure Monitor	IIa	41316438-03
PG-800BD-1	Electronic Blood Pressure Monitor	IIa	41316438-03
PG-800B3	Electronic Blood Pressure Monitor	IIa	41316438-03
PG-800B4	Electronic Blood Pressure Monitor	IIa	41316438-03
PG-800B4D	Electronic Blood Pressure Monitor	IIa	41316438-03
PG-800B5	Electronic Blood Pressure Monitor	IIa	41316438-03
PG-800B5-1	Electronic Blood Pressure Monitor	IIa	41316438-03
PG-800B6	Electronic Blood Pressure Monitor	IIa	41316438-03
PG-800B6D	Electronic Blood Pressure Monitor	IIa	41316438-03
PG-800B6-1	Electronic Blood Pressure Monitor	IIa	41316438-03
PG-800B8	Electronic Blood Pressure Monitor	IIa	41316438-03
PG-800B9	Electronic Blood Pressure Monitor	IIa	41316438-03
PG-800B10	Electronic Blood Pressure Monitor	IIa	41316438-03
PG-800B11	Electronic Blood Pressure Monitor	IIa	41316438-03
PG-800B12	Electronic Blood Pressure Monitor	IIa	41316438-03
PG-800B15	Electronic Blood Pressure Monitor	IIa	41316438-03
PG-800B16	Electronic Blood Pressure Monitor	IIa	41316438-03

PG-800B18	Electronic Blood Pressure Monitor	IIa	41316438-03
PG-800B19	Electronic Blood Pressure Monitor	IIa	41316438-03
PG-800B19L	Electronic Blood Pressure Monitor	IIa	41316438-03
PG-800B22	Electronic Blood Pressure Monitor	IIa	41316438-03
PG-800B23	Electronic Blood Pressure Monitor	IIa	41316438-03
PG-800B25	Electronic Blood Pressure Monitor	IIa	41316438-03
PG-800B26	Electronic Blood Pressure Monitor	IIa	41316438-03
PG-800B27	Electronic Blood Pressure Monitor	IIa	41316438-03
PG-800B28	Electronic Blood Pressure Monitor	IIa	41316438-03
PG-800B29	Electronic Blood Pressure Monitor	IIa	41316438-03
PG-800B31	Electronic Blood Pressure Monitor	IIa	41316438-03
PG-800B32	Electronic Blood Pressure Monitor	IIa	41316438-03
PG-800B33	Electronic Blood Pressure Monitor	IIa	41316438-03
PG-800B35	Electronic Blood Pressure Monitor	IIa	41316438-03
PG-800B36	Electronic Blood Pressure Monitor	IIa	41316438-03
PG-800B37	Electronic Blood Pressure Monitor	IIa	41316438-03
PG-800B41	Electronic Blood Pressure Monitor	IIa	41316438-03
PG-800B42	Electronic Blood Pressure Monitor	IIa	41316438-03
PG-800B43	Electronic Blood Pressure Monitor	IIa	41316438-03
PG-800B45	Electronic Blood Pressure Monitor	IIa	41316438-03
PG-800B46	Electronic Blood Pressure Monitor	IIa	41316438-03
PG-800B47	Electronic Blood Pressure Monitor	IIa	41316438-03

PG-800B51	Electronic Blood Pressure Monitor	IIa	41316438-03
PG-800B68	Electronic Blood Pressure Monitor	IIa	41316438-03
PG-800B69	Electronic Blood Pressure Monitor	IIa	41316438-03
PG-800A	Electronic Blood Pressure Monitor	IIa	41316438-03
PG-800AD	Electronic Blood Pressure Monitor	IIa	41316438-03
PG-800A-1	Electronic Blood Pressure Monitor	IIa	41316438-03
PG-800AD-1	Electronic Blood Pressure Monitor	IIa	41316438-03
PG-800A3	Electronic Blood Pressure Monitor	IIa	41316438-03
PG-800A4	Electronic Blood Pressure Monitor	IIa	41316438-03
PG-800A4D	Electronic Blood Pressure Monitor	IIa	41316438-03
PG-800A5	Electronic Blood Pressure Monitor	IIa	41316438-03
PG-800A6	Electronic Blood Pressure Monitor	IIa	41316438-03
PG-800A6D	Electronic Blood Pressure Monitor	IIa	41316438-03
PG-800A6-1	Electronic Blood Pressure Monitor	IIa	41316438-03
PG-800A6-2	Electronic Blood Pressure Monitor	IIa	41316438-03
PG-800A7	Electronic Blood Pressure Monitor	IIa	41316438-03
PG-800A7D	Electronic Blood Pressure Monitor	IIa	41316438-03
PG-800A8	Electronic Blood Pressure Monitor	IIa	41316438-03
PG-800A9	Electronic Blood Pressure Monitor	IIa	41316438-03
PG-800A11	Electronic Blood Pressure Monitor	IIa	41316438-03
PG-800A12	Electronic Blood Pressure Monitor	IIa	41316438-03
PG-800A15	Electronic Blood Pressure Monitor	IIa	41316438-03

PG-800A16	Electronic Blood Pressure Monitor	IIa	41316438-03
PG-800A18	Electronic Blood Pressure Monitor	IIa	41316438-03
PG-800A19	Electronic Blood Pressure Monitor	IIa	41316438-03
PG-800A25	Electronic Blood Pressure Monitor	IIa	41316438-03
PG-800A27	Electronic Blood Pressure Monitor	IIa	41316438-03
PG-800A28	Electronic Blood Pressure Monitor	IIa	41316438-03
PG-800A31	Electronic Blood Pressure Monitor	IIa	41316438-03
PG-800A32	Electronic Blood Pressure Monitor	IIa	41316438-03
PG-800A33	Electronic Blood Pressure Monitor	IIa	41316438-03
PG-800A35	Electronic Blood Pressure Monitor	IIa	41316438-03
PG-800A36	Electronic Blood Pressure Monitor	IIa	41316438-03
PG-800A37	Electronic Blood Pressure Monitor	IIa	41316438-03
PG-800A11-1	Electronic Blood Pressure Monitor	IIa	41316438-03
PG-800A36-1	Electronic Blood Pressure Monitor	IIa	41316438-03
PG-800A37-1	Electronic Blood Pressure Monitor	IIa	41316438-03
PG-800A51	Electronic Blood Pressure Monitor	IIa	41316438-03
PG-800A52	Electronic Blood Pressure Monitor	IIa	41316438-03
PG-2601B7	Neck Electronic Muscle Stimulator	IIa	41316438-03
PG-2601B6	Neck Electronic Muscle Stimulator	IIa	41316438-03
PG-2601B8	Neck Electronic Muscle Stimulator	IIa	41316438-03
PG-2601B9	Neck Electronic Muscle Stimulator	IIa	41316438-03
PG-2601B21	Neck Electronic Muscle Stimulator	IIa	41316438-03

PG-2601B22	Neck Electronic Muscle Stimulator	IIa	41316438-03
P6	Neck Electronic Muscle Stimulator	IIa	41316438-03
P7	Neck Electronic Muscle Stimulator	IIa	41316438-03

Table 2: Devices covered by this letter and for which the NB is NOT responsible for appropriate surveillance of the corresponding devices under the applicable Directive:

Ref Number/ Device Identification	Device Name	Device classification	MDD Certificate Reference(s)
N/A			

Confirmation Letter Revision History

Date	NB internal reference traceable to each version of the letter	Action