Declaration of Conformity

Manufacturer: ShenZhen Pango Medical Electronics Co., Ltd.

Manufacture Site: No.25, 1st Industry Zone, Fenghuang Road, Xikeng Village, Henggang Town, Longgang District, Shenzhen, , Guangdong, China

Additional site1: 2-4 Floor ,No.5 Shanzhuang Rd., Xikeng Village, Henggang Town, Longgang District, Shenzhen City, Guangdong Province, China

Zip Code: 518115

Tel: +86 755 3382 5988 Fax: +86 755 3382 5989

EC REP EC Representative: Lotus NL B.V.

Address：Koningin Julianaplein 10, 1e Verd, 2595AA, The Hague, Netherlands.

E-mail：peter@lotusnl.com

Tel：+31645171879 (English), +31626669008（Dutch）

Product: Electronic Blood Pressure Monitor

PG-800A Series Wrist Blood Pressure Monitor, Models: PG-800A, PG-800AD, PG-800A-1, PG-800AD-1, PG-800A3, PG-800A4, PG-800A4D, PG-800A5, PG-800A5D, PG-800A6, PG-800A6D, PG-800A6-1, PG-800A7, PG-800A7D, PG-800A9, PG-800A8, PG-800A11, PG-800A12, PG-800A15, PG-800A16, PG-800A18, PG-800A19, PG-800A25, PG-800A27, PG-800A28, PG-800A31, PG-800A32, PG-800A33, PG-800A35, PG-800A36, PG-800A36-1. PG-800A37, PG-800A37-1. PG-800A51.

PG-800B Series Upper arm Blood Pressure Monitor, Models: PG-800B, PG-800BD, PG-800B-1, PG-800BD-1, PG-800B3, PG-800B4, PG-800B4D, PG-800B5, PG-800B5-1, PG-800B6, PG-800B6D, PG-800B6-1, PG-800B9, PG-800B8, PG-800B10, PG-800B11, PG-800B12, PG-800B15, PG-800B16, PG-800B18, PG-800B19, PG-800B19L, PG-800B25, PG-800B22, PG-800B23, PG-800B26, PG-800B27, PG-800B28， PG-800B29, PG-800B31, PG-800B32, PG-800B33, PG-800B35, PG-800B36, PG-800B37, PG-800B41, PG-800B42, PG-800B43,PG-800B51, PG-800B68, PG-800B69.PG-800B45,PG-800B46,PG-800B47,PG-2601B7,PG-2601B6,PG-2601B8,PG-2601B9,PG-2601B21,PG-2601B22,P6,P7

Classification: (MDD, Annex Ⅸ): II a, Rule 10

UMDNS CODE: 16173

GMDN CODE: 45617

Contract number :

We herewith declare that the above mentioned products meet the provisions of the following EC Council Directives and Standards and conformity with the Swedish legislation LVFS 2003:11. All supporting documentations are retained under the premises of the manufacturer and the notify body.

The product concerned has been designed and manufactured under a quality management system according to Annex Ⅱ of Directive 93/42/EEC.

The declaration of conformity is issued under our own responsibility.

DIRECTIVES

General applicable directives:

Medical Device Directive: COUNCIL DIRECTIVE 93/42/EEC of 14 June 1993 concerning medical devices (MDD 93/42/EEC). Amended by DIRECTIVE 2007/47/EC of 5 September 2007

Standard:

All applicable harmonized Standards (published in the Official Journal of the European Communities)

Notified Body: Intertek Semko AB (Address: Box 1103, SE-164 22 Kista, Sweden) Code: 0413

Certificate: 41316438-03 Expiration date of the Certificate: 14 July 2023

Date CE mark was affixed:

Place No.25 1st Industry Zone, Fenghuang Rd, Xikeng village, Henggang town, Longgang District, Shenzhen, China

Name _____ DATE: 2021-07-05

General Manager

Position Head Regulatory Affairs, Management Representative