Declaration of Conformity

Manufacturer:

Xuzhou Yongkang Electronic Science Technology Co., Ltd

4F Building C8, 40 Jingshan Road, Economic and Technological

Development Zone, Xuzhou, China

European

Prolinx GmbH

Representative:

Brehmstr.56, 40239 Duesseldorf, GERMANY

Product Name:

Arm type blood pressure monitor

Models:

YK-BPA1, YK-BPA2, YK-BPA3, YK-BPA4

UMDNS Code:

16157

Classification (MDD, Annex IX): IIa, Rule 10 Conformity Assessment Route: Annex V.3

We herewith declare that the above mentioned products meet the transposition into national law, the provisions of the following EC Council Directives and Standards. All supporting documentations are retained under the premises of the manufacturer.

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

Notified Body:

TÜV SÜD Product Service GmbH, Ridlerstr. 65,

80339 München, Germany

NB Identification number:

0123

(EC) Certificate(s):

G2 17 09 92582 006

Expire date of the Certificate:

2022-04-27

Start of CE Marking:

2017-12-13

Place, Date of Issue:

Xuzhou city, 2017-12-13

Signature:

Name:

Zhao Xuecheng

Position:

General Manager