

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 Representative: **Prolinx GmbH**
Brehmstr. 56, 40239, Duesseeldorf, GERMANY

Product Name: **Fingertip Pulse Oximeter**
Models: **YK-80A, YK-80B, YK-80C, YK-81A, YK-81B, YK-81C, YK-82A, YK-82B,**
YK-82C, YK-83A, YK-83B, YK-83C, YK-84A, YK-84B, YK-84C, K1

UMDNS Code: **17148**

Classification (MDD, Annex IX): **Ila, Rule 10**

Conformity Assessment Route: **Annex II(excluding section 4) and Annex VII of Directive**
93/42/EEC

We herewith declare under our sole responsibility 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. A statement that the manufacturer is exclusively responsible for the DoC.

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): G1 092582 0009 Rev.00

Expire date of the Certificate: 2024-05-26

Start of CE Marking: 2019-11-26

Place, Date of Issue: Xuzhou, 2019-11-26

Signature:



Name: **Zhao Xuecheng**

Position: **General Manager**