

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, Duesse(dorf) 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

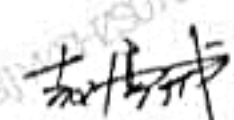
NB Identification number: 0123

(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

