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, Duesseldorf,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): **IIa，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**

徐州市永康电子科技有限公司 证件管理专用章 仅限 customs clearance 使用 再复印无效 编号