EC Declaration of Conformity

Manufacturer:	**Xuzhou Yongkang Electronic Science Technology Co., Ltd 1st&2nd Floor,6#01,6#02,No.6 Building 1st Phase Economic Development Manufacturing Zone,LIANDO U Valley, No.6 Leye Road ,Xuzhou ETDZ,221000 Xuzhou,PEOPLE'S REPUBLIC OF CHINA**
European Representative:	**Prolinx GmbH Brehmstr. 56, 40239 Düsseldorf 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,YK-81CEU
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

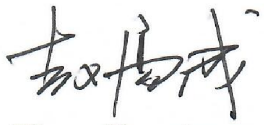
General applicable directives:

Directive 2011/65/EU of the European Parliament and of the Council of 8 June 2011 on the restriction of the use of certain hazardous substances in electrical and electronic equipment

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 GCQ 0925820011 Rev.00
Expire date of the Certificate:	2024-05-26
Confirmation Letter :	CL 092582 0014 Rev. 00
End date of extended validity:	2028-12-31

Issue date of the confirmation letter: 2023-10-31

Signature: 

Name: Zhao Xuecheng

Position: General Manager