

## EU DECLARATION OF CONFORMITY

Name and address of the 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**  
 SRN of manufacturer:/ **CN-MF-000018890**

Name and address of the EU Authorized Representative:/ **Prolinx GmbH**  
**Brehmstr. 56, 40239, Duesseldorf**  
**Germany**  
 SRN of EU Authorized Representative:/ **DE-AR-000005129**

**We declare under our sole responsibility that:**

Name of the medical device: / **Finger Clip Pulse Oximeter**

Trade name:/ **YONKER**

Product Model:/ **K1,YK-60A1,YK-60B1,YK-61A1,YK-61B1,YK-62A1,YK-62B1, YK-63A1,YK-63B1,YK-64A1,YK-64B1,YK-65A1,YK-65B1, YK-66A1,YK-66B1,YK-67A1,YK-67B1,YK-68A1,YK-68B1, YK-69A1,YK-69B1**

CND/EMDN:/ **Z1203020408 PULSE OXIMETERS**

Intended purpose:/ **The finger clip pulse oximeter can be used to measure human haemoglobin saturation and pulse rate of adult through finger.It is expected for hospitals, families, schools and medical centers.**

Basic UDI-DI:/ **69217452FCPORQ**  
 of class: / **Class IIa, Rule10**  
 according to annex VIII of Regulation (EU) 2017/745

Conformity assessment: / **Annex IX chapter I and chapter III**  
 according to Para.1 of Article 52(6) of Regulation (EU) 2017/745

Applicable standards:/ **EN ISO 13485: 2016+A11:2021**  
**EN ISO 14971: 2019**  
**EN ISO 20417:2021**  
**EN ISO 15223-1: 2021**  
**EN ISO 10993-1:2020**  
**EN ISO 10993-5: 2009**  
**EN ISO 10993-10:2023**  
**EN ISO 10993-23: 2021**  
**IEC 60601-1:2005/AMD1:2012/AMD2:2020**  
**IEC 60601-1-2:2014+AMD1:2020**  
**IEC 60601-1-11:2015/AMD1:2020**  
**EN ISO 80601-2-61:2019**  
**IEC 60601-1-6:2010+A1:2013+A2:2020**  
**EN 62366-1:2015+A1:2020**

EN 62304:2006+A1:2015  
EN ISO14155:2020

Other applicable Regulations  
& Directives:/

RoHS 2011/65/EU

CS reference: /

NONE

Notified Body: /

**DQS Medizinprodukte GmbH**  
**Address:August-Schanz-Straße 21 60433 FRANKFURT AM**  
**MAIN**

Notified Body Number:/

**0297**

Certificate No.: /

**31619822MDR2017Q**

Issue date of the Certificate:/

**2025-05-08**

Expire date of the Certificate:/

**2030-05-07**

XuZhou ,2025-06-20

Ort, Datum / Place, date /

Lieu, date / Luogo, data

Zhao Xuecheng, General Manager

Name und Funktion / Name and function /

Nom et fonction / Nome e funzione

