

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: / **Handheld Pulse Oximeter**

Trade name:/ **YONKER**

Product Model:/ **YK-820A,YK-820B**

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

Intended purpose:/ The Handheld Pulse Oximeter is intended for measuring and displaying the pulse rate, functional oxygen saturation (SpO2) and body temperature(optional). It is intended for spot checking and recording of SpO2, pulse rate , temperature in clinical institutions and homes. The Handheld Pulse Oximeter is not intended for active continuous monitoring.

Basic UDI-DI:/ **69217452HPO37**
 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
ISO 80601-2-56:2017+A1:2018
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

