



# EU Quality Management Certificate



This is to certify that the company

## 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  
Peoples Republic of China

SRN: CN-MF-000018890

has established, implemented and maintains a Quality Management System in accordance with

### **Annex IX, Chapter I and III of the Regulation (EU) 2017/745 Conformity Assessment based on a Quality Management System and on Assessment of Technical Documentation**

for the device categories and products listed in the Annex of this certificate.

The conformity of the Quality Management System has been verified in an audit and is subject to regular surveillance in accordance with Annex IX, Chapter 1, Section 3.  
Limitations to this certificate are listed in the Annex.

Devices listed in the Annex may bear the CE marking with the identification number of the Notified Body (0297).

For placing of devices of class III and devices class IIb implantable according to Article 52(4) subparagraph 2 listed in the Annex on the market, an additional certificate according to Annex IX, Chapter II is required.

Certificate registration no.	31619822 MDR2017Q
Certificate ID	1000246594
Effective date	2025-06-12
Expiry date	2030-05-07
Frankfurt am Main,	2025-06-12



Benannt durch/Designated by  
Zentralstelle der Länder  
für Gesundheitsschutz  
bei Arzneimitteln und  
Medizinprodukten  
www.zlg.de  
BS-MDR-094

## DQS Medizinprodukte GmbH

Heinrich von Mettenheim  
Managing Director



Accredited Body: DQS Medizinprodukte GmbH, August-Schanz-Str. 21, 60433 Frankfurt am Main  
**DQS Medizinprodukte GmbH is a Notified Body according to Regulation (EU) 2017/745  
of the Council concerning medical devices with the Identification Number 0297.**  
The validity of the certification can only be verified by the QR-code.



**Annex to EU Quality Management Certificate**  
**SRN of Manufacturer: CN-MF-000018890**  
**Certificate ID: 1000246594**

**Authorised Representative of the company:**

**Prolinx GmbH**

Brehmstr. 56  
40239 Düsseldorf  
Germany

SRN: DE-AR-000005129

**Device categories and variants covered by this certificate:**

Device category: **MDA 0203 - Active non-implantable devices for monitoring of vital physiological parameters**  
Product name: Finger Clip Pulse Oximeter  
Risk classification: IIa  
Basic-UDI-DI: 69217452FCPORQ  
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.

Device category: **MDA 0203 - Active non-implantable devices for monitoring of vital physiological parameters**  
Product name: Handheld Pulse Oximeter  
Risk classification: IIa  
Basic-UDI-DI: 69217452HPO37  
Intended purpose: The Handheld Pulse Oximeter is intended for measuring and displaying the pulse rate, functional oxygensaturation (SpO<sub>2</sub>), bodytemperature (optional). It is intended for spot checking and recording of SpO<sub>2</sub>, pulse rate, temperature in clinical institutions and homes. The Handheld Pulse Oximeter is not intended for active continuous monitoring.

**Examinations and tests performed:**

31619822\_A216384MED\_01 dated 2025-04-29  
31619822\_A215663MED\_Finger Clip Pulse Oximeter dated 2025-04-30  
31619822\_A215663MED\_Finger Clip Pulse Oximeter dated 2025-06-10

**Further conditions for or limitations to the validity of the certificate:**

n/a

**Reference to previous certificates:**

Revision	Date of Issue	Certificate-ID	Description of change
01	2025-05-08	1000211533	Correction product name in the technical file report.