

# EU QUALITY MANAGEMENT SYSTEM CERTIFICATE

Certificate no.  
6101GB448251210

Final Assessment Report no.  
6101AU18F

Effective date  
2025-12-10

Expiry date  
2028-11-26

This is to certify that the quality system of

**APK Technology Co., Ltd.**

6 Floor, Building B2, Industry of Hengfeng, No. 739, Zhoushi Road, Hezhou, Hangcheng Street,  
Bao'an District, Shenzhen, China

SRN: CN-MF-000011581

For design & development, manufacturing and final product inspection/testing of  
**Medical devices/groups of medical devices at locations as listed on the following pages**

has been assessed and found to comply with respect to

**The conformity assessment procedure described in Annex IX,  
Chapters I and III of Regulation (EU) 2017/745 on Medical Devices**

Any applicable limitations for certain medical devices are included in the following list or recorded  
in the final assessment report. This certification is subject to surveillance by DNV MEDCERT.

Place and date  
Hamburg, 2025-12-10

For the issuing office  
DNV MEDCERT GmbH – Notified Body 0482  
Pilatuspool 2, 20355 Hamburg, Germany



Benannt durch/Designated by  
Zentralstelle der Länder  
für Gesundheitsschutz  
bei Arzneimitteln und  
Medizinprodukten  
[www.zlg.de](http://www.zlg.de)

BS-MDR-096

The certificate is only valid when provided entirely with  
all of its pages. To verify the validity of this certificate,  
contact [medcert-info@dnv.com](mailto:medcert-info@dnv.com)

  
Anpika Chill  
Certification Body Operations



Certificate no.: [6101GB448251210](#)  
Place and date: [Hamburg, 2025-12-10](#)

### Authorised representative

Ruiyi Healthcare GrnbH  
Neuer Zollhof 3, 40221, Düsseldorf, Germany  
SRN: DE-AR-000005962

### Sites covered by this certificate

APK Technology Co., Ltd.

6 Floor, Building B2, Industry of Hengfeng, No. 739, Zhoushi Road, Hezhou, Hangcheng Street, Bao'an District, Shenzhen, China

APK Technology Co., Ltd.

802, 8 Floor, Building C6, Industry of Hengfeng, No. 739, Zhoushi Road, Hezhou, Hangcheng Street, Bao'an District, Shenzhen, China

### Preceding certificate

Certificate no.	Issue date	Identification of changes
N/A	N/A	N/A





Certificate no.: 6101GB448251210  
Place and date: Hamburg, 2025-12-10

## Products covered by this certificate

### Class I medical devices

For class I medical devices with a measuring function (class Im), the audit of the quality management system was limited to the aspects relating to the conformity of the devices with the metrological requirements.

Category	Class	Medical devices/groups of medical devices
MDA 0203	Im	Active non-implantable devices for monitoring of vital physiological parameters

### Class IIb medical devices

Category	EMDN code	Medical devices/groups of medical devices
MDA 0203	C900301	PULSE OXIMETER SENSORS

#### Intended purpose

SpO2 Sensor is used on corresponding parameter monitors or pulse oximeters by healthcare professionals to collect and transfer the SpO2 and pulse rate signals of the patient.

