

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



Benannt durch/Designated by
Zentralstelle der Länder
für Gesundheitsschutz
bei Arzneimitteln und
Medizinprodukten
www.zlg.de
BS-MDR-096

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


Anupika Chil
Certification Body Operations

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

Lack of fulfilment of conditions as set out in the Certification Agreement may render this Certificate invalid.

820111 EN Rev 7 2025.10.20

NOTIFIED BODY 0482: DNV MEDCERT GmbH
Pilatuspool 2, 20355 Hamburg, Germany, Tel +49 40 2263325-0, www.dnv.com



DNV

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



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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.

