

## Certificate

The Certification Body of TÜV Rheinland LGA Products GmbH

hereby certifies that the organization

ShenZhen ZhengKang Technology Co., Ltd. 2&3/F, Building A, No.3 FuXing Yi Lane HeHua Community, PingHu Street LongGang District ShenZhen 518100 Guangdong P.R. China

has established and applies a quality management system for medical devices for the following scope:

Manufacture and Distribution of Blood Pressure Monitors Electronic Infrared Thermometer, Pulseoximeter

Proof has been furnished that the requirements specified in

EN ISO 13485:2016

are fulfilled. The quality management system is subject to yearly surveillance.

Effective Date:

2020-04-16

Certificate Registration No.:

SX 60144981 0001

An audit was performed. Report No.: 17063021 002

This Certificate is valid until:

2022-12-24



Date 2020-04-16

and LGA Pro ÜWRheinland fizierungsst

Certification Body

Dipl.-Ing. I. Munkler

TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg Tel.: +49 221 806-1371 Fax: +49 221 806-3935 e-mail:cert-validity@de.tuv.com http://www.tuv.com/safety



## EC Certificate Directive 93/42/EEC Annex V Production Quality Assurance Medical Devices

Registration No.: DD 60144980 0001

Report No.: 17063021 002

Manufacturer: ShenZhen ZhengKang Technology

Co., Ltd.

2&3/F, Building A, No.3 FuXing Yi Lane

HeHua Community, PingHu Street

LongGang District

ShenZhen

518100 Guangdong

P.R. China

Products: Blood Pressure Monitors

**Expiry Date:** 2024-05-26

The Notified Body hereby declares that the requirements of Annex V of the directive 93/42/EEC have been met for the listed products. The above named manufacturer has established and applies a quality assurance system, which is subject to periodic surveillance, defined by Annex V, section 4 of the aforementioned directive. For placing on the market of class IIb and class III devices covered by this certificate an EC type-examination certificate according to Annex III is required.

**Effective Date:** 2020-04-16

Date: 2020-04-16

Dipl.-Ing. I. Munkler

**VRheinland** 

TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg
TÜV Rheinland LGA Products GmbH is a Notified Body according to Directive 93/42/EEC
concerning medical devices with the identification number 0197.