

Certificate of Conformity
NO.: 3015697152

This certifies that:

Applicant : SHENZHEN ZHENGKANG TECHNOLOGY CO., LTD.
2&3/F, Building A, No.3 FuXing Yi Lane, HeHua Community,
PingHu Street, LongGang District
Shenzhen

Manufacturer : SHENZHEN ZHENGKANG TECHNOLOGY CO., LTD.
2&3/F, Building A, No.3 FuXing Yi Lane, HeHua Community,
PingHu Street, LongGang District
Shenzhen

Device Listing : D393013 (Thermometer Kit)

EUT : Infrared Forehead Thermometer

Models : JZK-601, JZK-602, JZK-603

Test Standard : Food and Drug Administration Regulation

This certificate is issued to the above stated facility is registered with the U.S. Food and Drug Administration pursuant to the Federal Food Drug and Cosmetic Act, such registration does not constitute an endorsement by the U.S. Food and Drug Administration of the quality or value of the products, nor does it constitute a recommendation for the use of the products. The U.S. Food and Drug Administration does not confirm that such registration remains effective upon request and presentation of the certificate until December 31, 2020. Registration information can also be found on the FDA website at: <http://www.fda.gov/oc/registration>. For the U.S. Food and Drug Administration's complete registration number, administrator number, product model, and the website is: <http://www.fda.gov/oc/registration>.

FDA

Manager:
Oct. 17, 2019

NO.: 3015697152
ANNEX
Models

JZK-601

JZK-603

JZK-602

JZIKI

Form QAT_10-M05, version 00, effective since March 6th, 2020

Certificate of Compliance

No. 4M200326.SZTDD37

Certificate's Holder: ShenZhen ZhengKang Technology Co., Ltd.
2&3/F, Building A, No.3 FuXing Yi Lane, HeHua Community, PingHu Street, LongGang District, Shenzhen.

Certification ECM Mark:  Type Approved

Product: Infrared forehead thermometer
Model(s): Medical infrared thermometer

Verification to: Standard: EN 60601-1-2:2015, EN 60601-1:2006+A11:2011+A1:2013+A12:2014
related to CE Directive(s): 2014/35/EU (Low Voltage) 2014/30/EU (Electromagnetic Compatibility)

Remark: This document has been issued on a voluntary basis and upon request of the manufacturer. It is our opinion that the technical documentation received from the manufacturer is satisfactory for the requirements of the ECM Certification Mark. The conformity mark above can be affixed on the products according to the ECM regulation about its release and its use.

Additional information and clarification about the Marking:

CE The manufacturer is responsible for the CE Marking process. This document has been issued on the basis of the regulation on ECM Voluntary Mark for the certification of products. RG01_ECM rev 3 available at: www.entecema.it

Issuance date: 26 March 2020
Expiry date: 25 March 2025

Reviewer: Technical expert Amanda Payne
Approver: ECM Service Director Luca Bedonni

Ente Certificazione Macchine Srl
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CERTIFICATE of Compliance

This is to Certify that the
Medical Devices -- Quality Management System
of
SHENZHEN ZHENGKANG TECHNOLOGY CO., LTD
深圳市正康科技有限公司

2nd&3rd floor, Building A, NO.3, Lane 1, FuXing treet, HeHua Community,
PingHu Town, LongGang District, Shen Zhen, Guangdong
深圳市龙岗区平湖街道禾花社区福星一巷3号后A栋2、3楼

has been independently assessed and is compliant
with the requirements of
ISO 13485:2016

This Certificate is applicable to the following product or service ranges:
Production and sales of Electronic blood pressure monitor, Oximeter, Blood glucose meter,
Electronic thermometers, Pulse therapeutic apparatus, Myopia Treatment Instrument,
Facial beauty instrument, Massage products, Electronic breast pump, Breast enhancement
body sculpting instrument, Electrocardiogram machine, Heart pulse rate
monitor, Multi-parameter monitor
:: Certificate No :: TW50598U

Date of initial registration	09 April 2018
Date of this Certificate	09 April 2018
Surveillance audit on or before	08 April 2019
Recertification Due / Certificate expiry	08 April 2021

This Certificate is property of Stauchly Management & System Services Pvt. Ltd. and remains valid subject to satisfactory surveillance audits.

Stauchly
Director
STAUCHLY MANAGEMENT & SYSTEM SERVICES PVT. LTD.
UBO, 3rd Floor, Laxmi Nagar, Shakarpur, Delhi - 110002

ISO Net
www.iso-certification.com

For precise and updated information concerning the present certificate mail to: info@stauchlyservices.com
This Certificate is the property of Stauchly Management & System Services Private Limited and shall be returned immediately when demanded