

Certificate

The Certification Body of TÜV Rheinland LGA Products GmbH

hereby certifies that the organization

Hangzhou Sejoy Electronics & Instruments Co., Ltd. Area C, Building 2, No.365, Wuzhou Road Yuhang Economic Development Zone Hangzhou City 311100 Zhejiang P.R. China

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

(see attachment for scope and additional site included)

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:

2020-09-08

Certificate Registration No.:

SX 60149973 0001

An audit was performed. Report No.: 15067822 020

This Certificate is valid until:

2023-06-18

Certification Body



Date 2020-09-08

Herbert Zhong ertifizierung^s

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



TÜV Rheinland LGA Products GmbH Tillystraße 2, 90431 Nürnberg

Doc. 1/1, Rev. 0

Attachment to Certificate

Registration No.:

SX 60149973 0001

Report No.:

15067822 020

Organization:

Hangzhou Sejoy Electronics &

Instruments Co., Ltd.

Area C, Building 2, No.365, Wuzhou Road

Yuhang Economic Development Zone

Hangzhou City 311100 Zhejiang

P.R. China

Scope:

Manufacture and Distribution of Digital Thermometers, Infra-red Ear Thermometers, Blood Pressure Monitors,

Infrared Ear/Forehead Thermometers;

Design and Development, Manufacture and Distribution of Blood Glucose Meters, Blood Glucose Test Strips,

Glucose Test Controls, Hemoglobin Test Strips,

Hemoglobin Meters, Control Solution, Drug Abuse Reagent

Site included:

Hangzhou Sejoy Electronics & Instruments Co., Ltd. Building 2, No.202, Zhenzhong Road, West Lake Economy

& Technology Zone, Hangzhou 310030, China

Manufacture of Digital Thermometers, Infra-red Ear Thermometers, Blood Pressure Monitors, Infrared Ear/Forehead

Thermometers

Certification Body



Date: 2020-09-08

