TÜVRheinland®

Certificate

The Certification Body of
TÜV Rheinland LGA Products GmbH

hereby certifies that the organization

Ningbo Shangcun Electronic Co., Ltd.
No. 9 Yongning Rd., Yuyao
Ningbo
315400 Zhejiang
China

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

Design and Development, Manufacture, Distribution of Digital Thermometers, Infra-red Forehead Thermometers, Infra-red Ear Thermometers

Proof has been furnished that the requirements specified in

EN ISO 13485:2012
EN ISO 13485:2012/AC:2012

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

Effective Date:	2019-03-31
Certificate Registration No.:	SX 60114586 0001
An audit was performed. Report No.:	15096028 001
This Certificate is valid until:	2021-04-01

FIRMA DE PRODUCERE ȘI COMERȚ "SOGNO" S.R.L. REPUBLICA MOLDOVA, MUN. CHIȘINĂU
Sogno® S.R.L. IDNO 1004600013854

Certification Body

Digitally signed by Iarovoi Petru
Date: 2020.06.18 12:08:44 EEST
Reason: MoldSign Signature
Location: Moldova

DAkkS
Deutsche
Akkreditierungsstelle
D-ZM-14169-01-02

Date 2019-03-31

TÜV Rheinland LGA Products GmbH Zertifizierungsstelle TÜVRheinland®

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 II, excluding Section 4
Full Quality Assurance System
Medical Devices

Registration No.: HD 60114585 0001

Report No.: 15096028 001

Manufacturer:
Ningbo Shangcun Electronic
Co., Ltd.
No. 9 Yongning Rd., Yuyao
Ningbo
315400 Zhejiang
China

Products:
- Digital Thermometers
- Infra-red Forehead Thermometers
- Infra-red Ear Thermometers

Expiry Date: 2021-10-27

The Notified Body hereby declares that the requirements of Annex II, excluding section 4 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 II, section 5 of the aforementioned directive. For placing on the market of class III devices covered by this certificate an EC design-examination certificate according to Annex II, section 4 is required.

Notified Body

Effective Date: 2017-05-11

Date: 2017-05-11

Dipl.-Ing. I. Munkler

TÜV Rheinland LGA Products GmbH - Zertifizierungsstelle

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.

FIRMA DE PRODUCERE ȘI COMERȚ "SOGNO" S.R.L. * REPUBLICA MOLDOVA * Sogno S.R.L. IDNO 1004600013854 mun. CHIȘINĂU