

Nome commerciale: TERMOMETRO INFRAROSSI NON TOUCH

Codice Prodotto: TER-NTS

## Specification

Temperature units:

Celsius temperature(°C)/(°F), can be set

Measuring range:

Human body: (32.0~42.9°C)/(89.6~109.2)°F

Object: (0~118)°C/(32.~244.4)°F Accuracy: Human body:(35~42)°C

Outside ±0.3°C/±0.54°F(35~42)°C Within±0.2°C/±0.4°F

Object: ±1.0°C/±1.9°F



Forehead



One second measurement



Memory storage



Automatic shutdown





## **EC** Certificate

## Directive 93/42/EEC Annex II, excluding Section 4 Full Quality Assurance System Medical Devices

Registration No.: HD 60144431 0001

Report No.: 17063052 007

Manufacturer: Shenzhen BSX Technology

Electronics Co., Ltd.

Rm301.3F&4F 8th Building

LiHao Industrial Area

No. 78 AiNan Road, Longgang

ShenZhen

518116 Guangdong

P.R. China

Products: Bloo

Blood Pressure Monitors Infrared Thermometers

Replaces Approval, Registration No.: DD 60133947 0001

**Expiry Date:** 2023-12-09

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.

**Effective Date:** 

2020-03-12

Date:

2020-03-12

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.



## Certificate

The Certification Body of TÜV Rheinland LGA Products GmbH

hereby certifies that the organization

Shenzhen BSX Technology
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ShenZhen
518116 Guangdong
P.R. China

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

Design and Development, Manufacture and Distribution of Blood Pressure Monitors, Infrared Thermometers

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:

2020-03-12

Certificate Registration No.:

SX 60144432 0001

An audit was performed. Report No.: 17063052 007

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This Certificate is valid until:

2021-12-09

**Certification Body** 



Date 2020-03-12

Jason Pan III

TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg

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