

Wenzhou Yosun Medical Technology Co.,Ltd.

Address: No.17, Shahong Road. Lingmen, Beibaixiang Town. Yueqing, Wenzhou,
325603 Zhejiang, China
Tel: 0086 577 61896988 Fax: 0086 577 61896989

EC Declaration of Conformity

Manufacturer:

whose single Authorized Representative

Wenzhou Yosun Medical Technology Co.,Ltd.
No.17, Shahong Road. Lingmen, Beibaixiang Town.
Yueqing, Wenzhou, 325603 Zhejiang, China
TEL: 86-577-61896988 FAX: 86-577-61896988

LotusNL B.V.
Koningin Julianaplein 10,le Verd,
2595AA,The Hague,Netherlands
Tel: 31644168999

We, the manufacturer, herewith declare that the products

Product name: Digital Clinical Thermometer, Infrared Forehead Thermometers

Model:YD-101,YD-102,YD-103,YD-201,YD-202,YD-203,YD-205;

YI-100,YI-100A,YI-100B,YI-100C,YI-100D,YI-200,YI-300,YI-400

Product classification: Class IIa by rule 10

UMDNS-Code: [14-032]

Meet the provisions of Directive 93/42/EEC which apply to them.

The medical device has been assigned to class IIa according to Annex IX of the Directive 93/42/EEC .

It bears the mark CE0197

The product concerned has been designed and manufactured under a quality management system according to Annex V of Directive 93/42/EEC.

Compliance of the designed product with the Directive 93/42/EEC has been assessed and certified by the Notified Body

TUV Rheinland LGA Products GmbH

Tillystrabe 2 - 90431 Nurnberg

Registration No.: DD 60147731 0001 **Report No.:**15077861 007

Effective date: 2020-04-23

Expiry date: 2024-05-26

Following the procedure relating to the EC Declaration of Conformity set out in Annex V of Directive 93/42/EEC.

This Declaration of Conformity covers all medical devices as specified in the product list belonging to this declaration and is only valid in connection with a batch specific Certificate of Compliance for all products concerned bearing the CE mark 0197.

The above mentioned declaration of conformity is exclusively under the responsibility of

Company: Wenzhou Yosun Medical Technology Co.,Ltd.

Address: No.17, Shahong Road. Lingmen, Beibaixiang

Town. Yueqing,Wenzhou, ,325603 Zhejiang,China

Wenzhou China, Mar 15, 2020

Mr.Huang Liang Yuan, Manager



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

Registration No.: DD 60147731 0001

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Manufacturer: Wenzhou Yosun Medical Technology
Co., Ltd.
No. 17, Shahong Road, Lingmen
Beibaixiang Town, Yueqing
Wenzhou
325603 Zhejiang
P.R. China

Products:

- Digital Clinical Thermometers
- Infrared Forehead Thermometers

Replaces Approval, Registration No.: DD 60100326 0001

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: 2020-04-23

Date: 2020-04-23

Notified Body



Fuxiu Sheng

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.



CE DECLARATION OF CONFORMITY

Manufacturer : Wenzhou Yosun Medical Technology Co.,Ltd.

Address : No.17, Shahong Road, Lingmen, Beibaixiang Town, Yueqing, Wenzhou, Zhejiang 325603, China

Declares under its sole responsibility that the product:

NON CONTACT INFRARED THERMOMETER

Code No. YI-400

is in conformity with Directive 2011/65/EU of the European Parliament and of the Council of 8 June 2011 on the restriction of the use of certain hazardous substances in electrical and electronic equipment.

On behalf of :

Wenzhou Yosun Medical Technology Co.,Ltd.

Date and place :

2019/9/23

Name:

Huang Liangyuan

Title:

Manager

Signature:

Stamp :

