

Wenzhou Yosun Medical Technology Co.,Ltd.

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

Tel: 0086 577 61896988

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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:86-577-61896989
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Lotus NL B.V.
Address:Koningin Julianaplein 10,
le Verd,2595AA,The Hague,
Netherlands
Tel:31 645 171879

We, the manufacturer, herewith declare that the products

Product name:YI-400 Infrared Forehead Thermometers

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

Replaces Approval,Registration No.: DD 60100326 0001

Certificate No.: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, Apr 24,2020

Mr.Huang Liang Gui, (General Manager)

