

# EC Declaration of Conformity

*Manufacturer:*

*whose single Authorized Representative:*

Joint factory of Shanghai Huazhe International Co.,Ltd  
And JOYTECH Healthcare Co.ltd.  
Room F, 6/Floor, Building 6, No. 1369  
Dongfang Road, Shanghai, 200127, P. R China

Shanghai International Holding  
Corp. GmbH (Europe)  
Eiffestraße 80,20537  
Hamburg , Germany

We, the manufacturer, herewith declare that the products

Product name: **Infrared ear Thermometer**

**Type(s):**

Model: DET-101 (original model ET-101A), DET-102, DET103, DET-105, DET-1013, DET-1015

*UMDNS-Code:* **[14036]**

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



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

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

**TÜV SÜD Product Service GmbH**  
**Ridlerstraße 65 . 80339 Munich, Germany**  
Certificate No.: G10 109940 0002 Rev.00  
Valid from: 2023-08-24  
Valid until: 2027-04-27

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

This Declaration of conformity is valid in connection with the release document for the respective batch of produced devices.

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

Company: Shanghai Huazhe International Co., Ltd.

Address: Room F, 6/Floor, Building 6, No. 1369 Dongfang Road, Shanghai, 200127, P. R China

Shanghai Huazhe, China, 2023.OCT.17

上海华浙国际贸易有限公司  
SHANGHAI HUAZHE INTERNATIONAL CO.LTD  
Place, date

Mr. Jacky Zhu, manager

  
Legally binding signature, Function