

EC Declaration of Conformity

Manufacturer:

JOYTECH HEALTHCARE CO. LTD.

Address: No. 365, Wuzhou Road, Yuhang Economic Development Zone, Hangzhou city, 311100 Zhejiang P.R. China

Single Registration Number: CN-MF-000006020

whose single Authorized Representative:

**Shanghai International Holding Corp. GmbH
(Europe)**

Address: Eiffestrasse 80, 20537 Hamburg, Germany

Single Registration Number: DE-AR-000000001

We, the manufacturer, herewith declare that the products

Product Name: Infrared Ear Thermometer Model & Basic UDI-DI as table below:

| Models | Basic UDI-DI | EMDN-Code |
|--|--------------------|-------------|
| DET-101, DET-102, DET-103, DET-105, DET-1013, DET-1015, DET-1025, DET-1026 | 6970392211ET00012T | V0301010201 |
| DET-1115, DET-1215 | 6970392211ET00032X | V0301010201 |

Intended Purpose: The infrared ear thermometer is intended for the intermittent measurement of human body temperature. The device can be reused by people of all ages for home use and clinical use.

Common Specifications: Not Available.

covered by the present declaration is in conformity with this Regulation (EU) 2017/745 on medical device and, if applicable, with any other relevant Union legislation that provides for the issuing of an EU declaration of conformity.

The medical device has been assigned to **class IIa by rule 10 according** to Annex VIII of the (EU) 2017/745 MDR. It bears the mark

CE 0123

The product concerned has been evaluated under technical files compliance according to Annex II and Annex III, and manufactured under a quality management system according to Annex IX of (EU) 2017/745 MDR. All supporting documentation is retained at the premises of the manufacturer.

Compliance of the designated product with the (EU) 2017/745 MDR has been assessed and certified by the Notified Body

TÜV SÜD Product Service GmbH
Ridlerstraße 65, 80339 Munich, Germany, HRB 85742

Certificate No.: No.G10 109940 0002 Rev.01

Issue date: 2023-08-24

Expiry date: 2027-04-27

Notified body identified number: 0123

following the procedure relating to the EU Declaration of Conformity set out in Annex IV of (EU) 2017/745 MDR.

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

Company: **JOYTECH Healthcare Co., Ltd.**

JOYTECH HEALTHCARE CO., LTD
浙江健拓医疗仪器科技有限公司

Hangzhou, April 2nd, 2024

Place, date

Ren Yunhua General Manager

Legally binding signature, Function