

EU Declaration of Conformity

Manufacturer:

JOYTECH Healthcare Co., Ltd.

No. 365, Wuzhou Road, 311100 Hangzhou, Zhejiang

Province, PEOPLE'S REPUBLIC OF CHINA

Single Registration Number: CN-MF-000006020

whose single Authorized Representative:

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

Eiffestrasse 80, 20537 Hamburg, Germany

Single Registration Number: DE-AR-000000001

We, the manufacturer, herewith declare that the products

Product Name: Infrared Forehead Thermometer

Model&Basic UDI-DI as table below:

Models	Basic UDI-DI	EMDN-Code
DET-205, DET-206	6970392211ET000533	V0301010201
DET-305,DET-306,DET-3010,DET-3011,DET-3012,DET-3015,DET-3022,DET-3023,DET-3017,DET-3017a,DET-3018,DET-3018a,DET-3019,DET-3019a,DET-3020,DET-3021, 166103,TH1000	6970392211ET000635	V0301010202
DET-3024	6970392211ET00093B	

Intended Purpose: The infrared forehead thermometer is intended for the intermittent measurement of human body temperature from the skin surface of forehead. 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



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**

Certificate No.: No.G10 109940 0002

Valid from: 2024-07-05

Valid until: 2027-04-27

Date of Initial Issuance: 2022-04-28

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.**

Hangzhou, July 05, 2024

Place, date



Legalizing signature, title
General Manager