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-206	6970392211ET000533	V0301010201
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	
DET-306b, DET-3010b, DET-3011b, DET-3012b, DET-3015b, DET-3018b, DET-3018c, DET-3019b, DET-3019c, DET-3023b, DET-3020b	6970392211ET000737	
DET-3024b	6970392211ET000839	

Applicable Standards:

EN ISO 20417:2021	ISO 80601-2-56:2017	ISO 14155:2020
EN ISO 15223-1:2021	ISO 80601-2-56:2017/AMD1:2018	Regulation (EU)2017/745
EN ISO 14971:2019/A11:2021	IEC 62304:2006/A1:2015	Regulation (EU) 2020/561
CEN ISO/TR 24971-2020	EN ISO 10993-1:2020	Regulation (EU) 2023/607
IEC 60601-1:2005+AMD1:2012+AMD2:2020 CSV	EN ISO 10993-5:2009	Regulation (EU) 2023/1542
IEC 60601-1-2:2014+A1:2020	EN ISO 10993-10:2023	Regulation (EC) No.1907/2006
IEC 60601-1-6:2010+A1:2013+A2:2020	EN ISO 10993-23:2021	Directive 2011/65/EU
IEC 60601-1-11:2015+A1:2020;	EN ISO 20417:2021	
IEC 62366-1:2015/A1:2020	EN ISO 13485:2016	

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

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

Certificate No.: No.G10 109940 0002
Valid from: 2025-01-23
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, March 31, 2025

Place , date

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

Legally binding signature, title
Yunhua Ren, General Manager