EC Declaration of Conformity

Manufacturer:

JOYTECH HEALTHCARE CO. LTD.

Address: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)

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*	GMDN-*Code*
DET-101,DET-102,DET-103,DET-105,DET-1013, DET-1015,DET-1025,DET-1026	6970392211ET00012T	V0301010201	17887
DET-1115,DET-1215	6970392211ET00032X		
DET-1013b,1015b，1025b,1026b	6970392211ET00022V		
DET-1115b,1215b	6970392211ET00042Z		

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 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
Issue date: 2025-07-16
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,July 31, 2025	**Ren Yunhua General Manager**
Place , date	*Legally binding signature, Function*