

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

whose single Authorized Representative:

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

We, the manufacturer, herewith declare that the products

Digital Thermometer

Model: DMT series

UMDNS-Code: 14035

meet the provisions of Directive 93/42/EEC which apply to them.

The medical device has been assigned to class IIa by rule 10 according to Annex IX of the Directive 93/42/EEC.

It bears the mark

CE 0197

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 assured via assessment of the quality management system by the Notified Body.

TÜV Rheinland LGA Products GmbH
Tillystraße 2, 90431, Nürnberg, Germany

Certificate No.: DD60147728 0001

Issue date: 2020-04-07

Expiry date: 2024-05-26

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: JOYTECH HEALTHCARE CO., LTD.

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

Hangzhou, May 2th, 2022

Place, date



Applicable Standards

Digital Thermometer DMT series(Except DMT-4751,DMT-4752,DMT-4735b, DMT-4750) comply with the following standards or requirements:

NO.	Standards	
1	ISO 80601-2-56:2017+AMD1:2018	Medical electrical equipment -- Part 2-56: Particular requirements for basic safety and essential performance of clinical thermometers for body temperature measurement
2	EN60601-1:2006+A11:2011+A 1:2013+A12:2014	Medical electrical equipment -- Part 1: General requirements for safety
3	EN 60601-1-2:2015	Medical electrical equipment -- Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests
4	EN 60601-1-11:2015	MEDICAL ELECTRICAL EQUIPMENT-Part 1-11:General requirements for basic safety and essential performance - Collateral Standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment
5	EN 60601-1-6: 2010	Medical electrical equipment -- Part 1-6: General requirements for basic safety and essential performance - Collateral Standard: Usability
6	EN 62366:2008+A1:2015	Medical devices - Application of usability engineering to medical devices
7	EN ISO 14971:2012	Medical devices - Application of risk management to medical devices
8	EN 1041:2008+A1:2013	Information supplied by the manufacturer of medical devices
9	EN ISO 15223-1:2016	Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements
10	EN ISO 10993-1:2009/AC : 2010	Biological evaluation of medical devices - Part 1: Evaluation and testing
11	EN ISO 10993-5:2009	Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity

12	EN ISO 10993-10:2010	Biological evaluation of medical devices - Part 10: Tests for irritation and delayed-type hypersensitivity
13	EN ISO 13485:2016	Medical device-Quality management systems – Requirements for regulatory purpose
14	IEC 62304:2006+AMD1:2015	Medical device software - Software life cycle processes

Digital Thermometer DMT-4751,DMT-4752,DMT-4735b,DMT-4750 comply with the following standards or requirements:

NO.	Standards	
1	ISO 80601-2-56:2017+AMD1:2018	Medical electrical equipment -- Part 2-56: Particular requirements for basic safety and essential performance of clinical thermometers for body temperature measurement
2	EN60601-1:2006+A11:2011+A1:2013+A12:2014	Medical electrical equipment -- Part 1: General requirements for safety
3	EN 60601-1-2:2015	Medical electrical equipment -- Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests
4	EN 60601-1-11:2015	MEDICAL ELECTRICAL EQUIPMENT-Part 1-11:General requirements for basic safety and essential performance - Collateral Standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment
5	EN 60601-1-6: 2010	Medical electrical equipment -- Part 1-6: General requirements for basic safety and essential performance - Collateral

		Standard: Usability
6	EN 62366:2008+A1:2015	Medical devices - Application of usability engineering to medical devices
7	ETSI EN 300 328	Electromagnetic compatibility and Radio spectrum Matters (ERM); Wideband transmission systems; Data transmission equipment operating in the 2,4 GHz ISM band and using wide band modulation techniques; Harmonized EN covering the essential requirements of article 3.2 of the R&TTE Directive
8	ETSI EN 301 489-17	Electromagnetic compatibility and Radio spectrum Matters (ERM); ElectroMagnetic Compatibility (EMC) standard for radio equipment; Part 17: Specific conditions for Broadband Data Transmitting Systems
9	EN ISO 14971:2012	Medical devices - Application of risk management to medical devices
10	EN 1041:2008+A1:2013	Information supplied by the manufacturer of medical devices
11	EN ISO 15223-1:2016	Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements
12	EN ISO 10993-1:2009/AC : 2010	Biological evaluation of medical devices - Part 1: Evaluation and testing
13	EN ISO 10993-5:2009	Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity
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16	IEC 62304:2006+AMD1:2015	Medical device software - Software life cycle processes

Manufacturers Declaration of Identity (產品一致性聲明書)

We, manufacturer : (我們, 製造商)	JOYTECH HEALTHCARE CO., LTD.
Hereby declare that our product model (於此聲明我們的產品類別為) :	Digital thermometer
Our model reference number (我們的參考型號為) :	DMT-4338
Is technical identical with Rossmax International Ltd. 's model (與....)的型號在技術上保持一致)	TG380
Signed on behalf of Manufacturer (工廠代表簽名)	
Name in print	任云华
Date (日期) :	2018.03.08