JiangSu YuYue Medical Equipment & Supply CO., LTD.

Section 11
Document of Conformity

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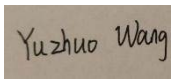
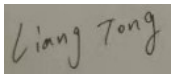
Edition/revision:	**A/0**
Status of control:	**Get control**
Issuing date:	**2019.9.26**
Prepared by:	
Reviewed by:	
Approved by:	

Declaration of Conformity

Manufacturer: **Name:JiangSu YuYue Medical Equipment & Supply CO., LTD.**
Address: Yunyang Industrial Park, Danyang City, Jiangsu Province ,China . 212300

European Representative:

Name: Shanghai International Holding Corp.GmbH(Europe)
Address: Eiffestrasse 80,20537 Hamburg Germany
VAT: DE 166 892 350

Product Category: Non-contact Infrared Forehead Thermometer

Model: YT-1/YT-2/YT-1B/YT-1C

UMDNS Code: 17888

Classification: IIa based on MDD 93/42/EEC annex IX rule 10

Conformity Assessment Route: **MDD Annex V**

We declare the compliance of the above medical device with the applicable requirements of Medical Device Directive: COUNCIL DIRECTIVE 93/42/EEC OF 14 JUNE 1993 CONCERNING MEDICAL DEVICES (MDD 93/42/EEC).All the supporting documents and files are retained under the premises of the manufactures. We are exclusively responsible for the Declaration of Conformity.

Notified Body: TÜV SÜD Product Service GmbH, Ridlerstr.65, 80339München, Germany

Notified Body Number: 0123

(EC) Certificate(s): G2 055329 0025 Rev.00

Expire date of the Certificate: May,26th,2024

Start of CE Marking: Feb,20th, 2020

Place, Date of Issue: DanYang, Jiangsu, P.R.CHINA

Signature: _____

JIANGSU YUYUE MEDICAL EQUIPMENT & SUPPLY CO.,LTD
江苏鱼跃医疗设备股份有限公司

Name: Dong Jin Ouyang

Position: Management Representative

List of EU harmonized and international standards

S/N	Ref. No.	Edition No.	Title
1	93/42/EEC	2007/47/EC	Medical Device Directives of EU
2	EN ISO 13485	2012	Medical devices-Quality management systems-Requirements for regulatory purposes
3	EN ISO 14971	2012	Medical devices-Application of risk management to medical devices
4	ISO10993-1	2009	Biological evaluation of medical devices -- Part 1: Evaluation and testing within a risk management process
5	ISO 10993-5	2009	Biological evaluation of medical devices -- Part 5: Tests for in vitro cytotoxicity
6	ISO 10993-10	2010	Biological evaluation of medical devices -- Part 10: Test for Irritation and delayed-type hypersensitivity
7	EN 1041	2008	Terms, Symbols and Information concerning Medical Device ---- Information Supplied by the Manufacturer with Medical Devices
8	ISO 15223-1	2016	Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied -Part 1: General requirements
9	IEC 60601-1	2005+A1：2012	Medical electrical equipment — Part 1: General requirements for basic safety and essential performance
10	IEC 60601-1-2	2014	Medical electrical equipment — Part 1-2: General requirements for basic safety and essential performance — Collateral standard: Electromagnetic compatibility — Requirements and tests
11	IEC 60601-1-8	2006+A1：2012	Medical electrical equipment — Part 1-8: General requirements for basic safety and essential performance–Collateral Standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systemsform
12	IEC 60601-1-11	2015	Medical electrical equipment — Part 1: General requirements for basic safety and essential performance - Collatral standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment
13	ISO80601-2-69	2014	Medical electrical equipment—Part 2-69: Particular requirements for basic safety and essential performance of oxygen concentrator equipment

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江苏鱼跃医疗设备股份有限公司