

Section 11

Document of Conformity

No.:	YY-TCF.DZ-YT-1-0024
Edition/revision:	A/0
Status of control:	Get control
Issuing date:	2019.9.26
Prepared by:	Yuzhuo Wang
Reviewed by:	Liang Tong
Approved by:	Can Chai

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-1A/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, 80339 München, Germany

Notified Body Number: 0123

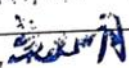
(EC) Certificate(s): G2 055329 0022 REV.02

Expire date of the Certificate: 2020-11-10

Start of CE Marking: 2019-04-13

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

JIANGSU YUYUE MEDICAL EQUIPMENT & SUPPLY CO. LTD.
江苏山岳医疗设备有限公司

Signature: 

Name: Dong Jin Ouyang

Position: Management Representative