

EU Declaration of Conformity

Manufacturer: JIANGSU YUYUE MEDICAL EQUIPMENT & SUPPLY CO., LTD.

Address: No.1 Baisheng Road Development Zone, Danyang, Jiangsu 212300 CHINA

SRN: CN-MF-000012834

European Representative:

Name: Metrax GmbH

Address: Rheinwaldstr. 22, 78628 Rottweil, GERMANY

SRN: DE-AR-000005481

Product Category:	Infrared ear thermometer
Model:	YHT101
Intended purpose:	The intended purpose of the device is to display the body temperature in the ear cavity by thermal radiation. It is intended for use on infants (except for pre-term babies or small for gestational age babies), children and adults.
Classification:	Class IIa based on MDR 2017/745 Annex VIII rule 10
Basic UDI-DI:	693325792208HW
Conformity Assessment Route:	MDR Annex IX chapter I, chapter III and Section 4

We declare that above mentioned products meet the provision of the following EC Council Directive and Regulation. All the supporting documents and files are retained under the premises of the manufacture. We are exclusively responsible for the Declaration of Conformity. There is no applicable common specifications for infrared ear thermometer.

General applicable directives and regulation:

Medical Device Regulation (EU) 2017/745

RoHS Directive 2011/65/EU Annex II and its amendment (EU) 2015/863

REACH (Registration, Evaluation, Authorisation and Restriction of Chemicals) REGULATION (EC) No 1907/2006

WEEE Directive 2012/19/EU

Notified Body: DQS Medizinprodukte GmbH

Notified Body Number: 0297

(EC) Certificate(s): 550975 MDR2017Q

Expire date of the Certificate: Dec. 27, 2028

Start of CE Marking (MDD): Nov. 21, 2020

Start of CE Marking (MDR): Oct. 22, 2024

Signature: 

Name: Jie Mei

Position: **Person Responsible for Regulatory Compliance**

Place: DanYang, Jiangsu, P.R. CHINA

Issue Date: Jan.15, 2025