



EU Quality Management Certificate



This is to certify that the company

Jiangsu Yuyue Medical Equipment & Supply CO., LTD.

No.1 Baisheng Road Development Zone
212300 Danyang, Jiangsu
China

SRN: CN-MF-000012834

has established, implemented and maintains a Quality Management System in accordance with

Annex IX, Chapter I and III of the Regulation (EU) 2017/745 **Conformity Assessment based on a Quality Management System and on Assessment of** **Technical Documentation**

for the device categories and products listed in the Annex of this certificate.

The conformity of the Quality Management System has been verified in an audit and is subject to regular surveillance in accordance with Annex IX, Chapter 1, Section 3.
Limitations to this certificate are listed in the Annex.

Devices listed in the Annex may bear the CE marking with the identification number of the Notified Body (0297).

For placing of devices of class III and devices class IIb implantable according to Article 52(4) subparagraph 2 listed in the Annex on the market, an additional certificate according to Annex IX, Chapter II is required.

Certificate registration no.	550975 MDR2017Q
Certificate ID	1000170234
Effective date	2024-08-15
Expiry date	2028-12-27
Frankfurt am Main,	2024-08-15



DQS Medizinprodukte GmbH

Sigrid Uhlemann
Managing Director

Michael Bothe
Head of Certification Body
(active medical devices)

Szymon Kurdyn
Head of Certification Body
(non-active medical devices)



Accredited Body: DQS Medizinprodukte GmbH, August-Schanz-Str. 21, 60433 Frankfurt am Main
DQS Medizinprodukte GmbH is a Notified Body according to Regulation (EU) 2017/745
of the Council concerning medical devices with the Identification Number 0297.
The validity of this certificate can only be verified by the QR-code.



Annex to EU Quality Management Certificate
SRN of Manufacturer: CN-MF-000012834
Certificate ID: 1000170234

Authorised Representative of the company:

Metrax GmbH

Rheinwaldstr. 22,
78628 Rottweil,
Germany

SRN: DE-AR-000005481

Device categories and variants covered by this certificate:

Device category: **MDA 0203 - Active non-implantable devices for monitoring of vital physiological parameters**

Product name: Infrared ear thermometer YHT100/YHT103

Risk classification: IIa

Basic-UDI-DI: 693325792313HU

Intended purpose: The intended use 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.

Device category: **MDN 1208 - Non-active non-implantable instruments**

Product name: Probe Cover YE20

Risk classification: IIa

Basic-UDI-DI: 693325792677K5

Intended purpose: The probe cover is used as a sanitary barrier between the infrared ear thermometer and the ear canal.

Device category: **MDA 0203 - Active non-implantable devices for monitoring of vital physiological parameters**

Product name: Infrared thermometer YT-3

Risk classification: IIa

Basic-UDI-DI: 693325792315HY

Intended purpose: This device is used to measure the forehead temperature of the human body, it is intended for use on people of all ages except pre-term babies or very small (small for gestational age) babies.

Device category: **MDA 0203 - Active non-implantable devices for monitoring of vital physiological parameters**

Product name: Infrared thermometer YHW-5

Risk classification: Class IIa

Basic-UDI-DI: 693325792316J2

Intended purpose: This device is used to measure the forehead temperature of the human body, it is intended for use on people of all ages except pre-term babies or very small (small for gestational age) babies.



Annex to EU Quality Management Certificate
SRN of Manufacturer: CN-MF-000012834
Certificate ID: 1000170234

Device category:	MDA 0203 - Active non-implantable devices for monitoring of vital physiological parameters
Product name:	Infrared thermometer YT-1
Risk classification:	Class IIa
Basic-UDI-DI:	693325792210HH
Intended purpose:	The Infrared thermometer is a nonsterile, reusable clinical thermometer intended for measuring the human body temperature in non-contact mode on the center of the forehead as the measurement site on people of all ages except preterm babies or very small (small for gestational age) babies
Device category:	MDA 0203 - Active non-implantable devices for monitoring of vital physiological parameters
Product name:	Infrared ear thermometer YHT101
Risk classification:	Class IIa
Basic-UDI-DI:	693325792208HW
Intended purpose:	The intended use 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.
Device category:	MDA 0203 - Active non-implantable devices for monitoring of vital physiological parameters
Product name:	Infrared thermometer YHW-6
Risk classification:	Class IIa
Basic-UDI-DI:	693325792066J2
Intended purpose:	This device is used to measure the forehead temperature of the human body, it is intended for use on people of all ages except pre-term babies or very small (small for gestational age) babies.

Examinations and tests performed:

550975_A212927MED_01 dated 2023-10-12

550975_A212438MED_02 dated 2023-12-18

Further conditions for or limitations to the validity of the certificate:

n/a

Reference to previous certificates:

Revision	Date of Issue	Certificate-ID	Description of change
01	2023-12-28	1000126662	New certificate template and Addition of the products Infrared thermometer YT-1, Infrared ear thermometer YHT101 and Infrared thermometer YHW-6