

EC Certificate
Directive 93/42/EEC Annex V
Production Quality Assurance
Medical Devices

Registration No.: DD 60147728 0001

Report No.: 15095961 011

Manufacturer: JOYTECH Healthcare Co., Ltd.
No. 365, Wuzhou Road
Yuhang Economic Development Zone
Hangzhou City
311100 Zhejiang
P.R. China

Products:

- Digital Thermometers
- Blood Pressure Monitors
- Infrared Ear Thermometers
- Infrared Forehead Thermometers
- Infrared Ear/Forehead Thermometers
- Electric Breast Pumps

Replaces Approval, Registration No.: DD 60128148 0001

Expiry Date: 2024-05-26

The Notified Body hereby declares that the requirements of Annex V of the directive 93/42/EEC have been met for the listed products. The above named manufacturer has established and applies a quality assurance system, which is subject to periodic surveillance, defined by Annex V, section 4 of the aforementioned directive. For placing on the market of class IIb and class III devices covered by this certificate an EC type-examination certificate according to Annex III is required.

Effective Date: 2020-04-07

Date: 2020-04-07

Notified Body

Jason Pan



TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg
TÜV Rheinland LGA Products GmbH is a Notified Body according to Directive 93/42/EEC
concerning medical devices with the identification number 0197.



**Add value.
Inspire trust.**

TÜV SÜD Product Service GmbH · Ridlerstr. 65 · 80339 Munich · Germany

JOYTECH Healthcare Co., Ltd.
No.365, Wuzhou Road
311100 HANGZHOU, ZHEJIANG PROVINCE
PEOPLE'S REPUBLIC OF CHINA

Your reference/letter of	Our reference/name	Tel. extension/Email	Fax extension	Date	Page
109940	CAC-TPS0083 713301778 713317081	medical_devices@tuvsud.com	N/A	2024-04-03	1 of 5

**TÜV SÜD Product Service GmbH
Confirmation Letter
CL 109940 0034 Rev. 00**

Reference: CAC-TPS0083 | 713301778 | 713317081

To whom it may concern,

Confirmation of the status of a formal application, written agreement, and appropriate surveillance in the framework of Regulation EU 2023/607 amending Regulations (EU) 2017/745 (in the following referenced as MDR) as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices.

With this letter TÜV SÜD Product Service GmbH, designated under MDR and identified by the number 0123 on NANDO, confirms that we have received a formal application in accordance with Section 4.3, first subparagraph of Annex VII of MDR and has signed a written agreement in accordance with Section 4.3, second subparagraph of Annex VII of MDR with the above stated manufacturer with the following SRN Number:

SRN Number: CN-MF-000006020

The devices covered by the formal application and the written agreement mentioned above are identified in the Tables below.

- Table 1 identifies the devices for which an MDR application has been received, written agreement concluded and for which TÜV SÜD Product Service GmbH is also responsible for appropriate surveillance of the corresponding devices under the applicable Directive.
- Table 2 identifies the devices for which an MDR application has been received and a written agreement concluded, but TÜV SÜD Product Service GmbH has not yet taken the responsibility for appropriate surveillance of the corresponding devices under the applicable Directive.

Registered Office: Munich
Trade Register Munich HRB 85 742
UniCredit Bank AG · BIC HYVEDEMMXXX
IBAN DE13 7002 0270 0048 8522 11
VAT ID No. DE129484267
Information pursuant to § 2 [1] DL-InfoV
(Germany) at tuvsud.com/imprint

Supervisory Board:
Holger Lindner (Chairman)
Board of Management:
Walter Reithmaier (CEO)
Patrick van Welij

TÜV SÜD Product Service GmbH
Certification body for medical Products
Ridlerstr. 65
80339 Munich
Germany

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If devices covered by certificates issued under Directive 90/385/EEC (AIMDD) or Directive 93/42/EEC (MDD) that expired after 26 May 2021 and before 20 March 2023, without having been withdrawn, this letter also confirms that:

- the manufacturer signed the written agreement under MDR by the date of MDD/AIMDD certificate expiry; or
- provided evidence that a competent authority of a Member State had granted a derogation or exemption from the applicable conformity assessment procedure in accordance with Article 59(1) of MDR or Article 97(1) of the MDR respectively.

The transition timelines in accordance Article 120 (3) of MDR that apply to the devices covered by this letter, subject to the manufacturer's continued compliance to the other conditions specified in Article 120 (3c) of MDR, are shown below:

- 26 May 2026 for Class III custom-made implantable devices
- 31 December 2027 for Class III devices and Class IIb implantable devices (except sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips and connectors)
- 31 December 2028 for other Class IIb devices, Class IIa, Class I devices placed on the market in sterile condition, measuring function.
- 31 December 2028 for devices not requiring the involvement of a notified body under MDD but requiring it under MDR (e.g., class I devices that qualify as re-usable surgical instruments)

We reserve the right to invoice any issuance, copies, amendments and / or changes of the confirmation letter according to effort.

For confirmation letter validity see www.tuvsud.com/ps-cert?q=CL_109940_0034_Rev._00

In case of inquiries please contact medical_devices@tuvsud.com.

On behalf of the Notified Body TÜV SÜD Product Service GmbH,

3rd April 2024.

TÜV SÜD Product Service GmbH
Medical and Health Services

Shuping Zhu

Ms. Shuping Zhu
Conformity Assessment Responsible (CARE)

TÜV SÜD Product Service GmbH
Medical and Health Services

A blue ink signature of Tunde Junaid, written in a cursive style.

Tunde Junaid
2024.04.03
12:49:19 +02'00'

Tunde Junaid
Application Reviewer



Table 1: Devices covered by this letter and for which TÜV SÜD Product Service GmbH is also responsible for appropriate surveillance of the corresponding devices under the applicable Directive: N/A

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified during application review)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification

Table 2: Devices covered by this letter and for which TÜV SÜD Product Service GmbH is NOT responsible for appropriate surveillance of the corresponding devices under the applicable Directive:

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified during application review)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
Device 1 Digital Thermometers (Basic UDI -DI: 6970392211MT000163, 6970392211MT000265, 6970392211MT000367, 6970392211MT000469, 6970392211MT00056B, 6970392211MT00066D, 6970392211MT00076F, 6970392211MT00086H, 6970392211MT00096K, 6970392211MT001064, 6970392211MT001166, 6970392211MT001268, 6970392211MT00136A, 6970392211MT00146C)	☐ Class III ☐ Class IIb implantable (non-exempted) ☐ Class IIb / Class IIb implantable (exempted) ☒ Class IIa ☐ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class III implantable custom-made-device ☐ Class I reusable surgical instruments	☒ N/A	☒ Certification as follows: Certificate # No.: DD 60147728 0001; NB# 0197
Device 2 Blood Pressure Monitors (Basic UDI -DI: 6970392211BP0001Y5, 6970392211BP0002Y7, 6970392211BP0003Y9, 6970392211BP0004YB, 6970392211BP0005YD, 6970392211BP0006YF, 6970392211BP0007YH)	☐ Class III ☐ Class IIb implantable (non-exempted) ☐ Class IIb / Class IIb implantable (exempted) ☒ Class IIa ☐ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class III implantable custom-made-device ☐ Class I reusable surgical instruments	☒ N/A	☒ Certification as follows: Certificate # No.: DD 60147728 0001; NB# 0197
Device 3	☐ Class III	☒ N/A	☒ Certification as follows:



Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified during application review)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
Infrared Ear Thermometers (Basic UDI -DI: 6970392211ET00012T, 6970392211ET00022V)	☐ Class IIb implantable (non-exempted) ☐ Class IIb / Class IIb implantable (exempted) ☒ Class IIa ☐ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class III implantable custom-made-device ☐ Class I reusable surgical instruments		Certificate # No.: DD 60147728 0001; NB# 0197
Device 4 Infrared Forehead Thermometers (Basic UDI -DI: 6970392211ET000533, 6970392211ET000635, 6970392211ET000737)	☐ Class III ☐ Class IIb implantable (non-exempted) ☐ Class IIb / Class IIb implantable (exempted) ☒ Class IIa ☐ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class III implantable custom-made-device ☐ Class I reusable surgical instruments	☒ N/A	☒ Certification as follows: Certificate # No.: DD 60147728 0001; NB# 0197
Device 5 Infrared Ear/Forehead Thermometers (Basic UDI -DI: 6970392211ET00102U)	☐ Class III ☐ Class IIb implantable (non-exempted) ☐ Class IIb / Class IIb implantable (exempted) ☒ Class IIa ☐ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class III implantable custom-made-device ☐ Class I reusable surgical instruments	☒ N/A	☒ Certification as follows: Certificate # No.: DD 60147728 0001; NB# 0197
Device 6 Electric Breast Pumps (Basic UDI -DI: 6970392211LD0002Y5)	☐ Class III ☐ Class IIb implantable (non-exempted) ☐ Class IIb / Class IIb implantable (exempted) ☒ Class IIa	☒ N/A	☒ Certification as follows: Certificate # No.: DD 60147728 0001; NB# 0197



Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified during application review)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
	☐ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class III implantable custom-made-device ☐ Class I reusable surgical instruments		

Confirmation Letter Revision History

Date	TÜV SÜD Product Service GmbH internal reference traceable to each version of the letter	Action
2024/04/03	CAC-TPS0083 713301778 713317081	Initial issue