TÜVRheinland®

EC Certificate

Directive 93/42/EEC Annex II, excluding Section 4
Full Quality Assurance System
Medical Devices

Registration No.: HD 60147882 0001

Report No.: 17057653 014

Manufacturer:
Shenzhen Dongdixin Technology
Co., Ltd.
Floor 1-2, No.3 Building,
Fanshen Xusheng Industrial Estate
Xilixiaobaimang
518108 Nanshan District, Shenzhen
P.R. China

Products: Medical Devices

(see attachment for products and additional sites included)

Replaces Approval, Registration No.: HD 60138391 0001

Expiry Date: 2024-05-26

The Notified Body hereby declares that the requirements of Annex II, excluding section 4 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 II, section 5 of the aforementioned directive. For placing on the market of class III devices covered by this certificate an EC design-examination certificate according to Annex II, section 4 is required.

Notified Body

TÜV Rheinland LGA Products GmbH Zertifizierungsstelle

Dipl.-Ing. W. Hsu

Effective Date: 2020-08-03

Date: 2020-08-03

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.

TÜVRheinland®

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Attachment to Certificate
Registration No.: HD 60147882 0001
Report No.: 17057653 014

Manufacturer: Shenzhen Dongdixin Technology Co., Ltd.
Floor 1-2, No.3 Building,
Fanshen Xusheng Industrial Estate
Xilixiaobaimang
518108 Nanshan District, Shenzhen
P.R. China

Products:
- Clinical Electronic Thermometers
- Infrared Ear/Forehead Thermometers
- Infrared Ear Thermometers
- Infrared Forehead Thermometers
- Nerve and Muscle Stimulators
- Electrical Acupuncture Stimulators
- Transcutaneous Electrical Nerve Stimulators
- Electrical Muscle Stimulators
- Electrical Neuromuscular Incontinence Stimulators
- Ultrasound Physical Therapy Devices
- Ultrasound and Electrical Neuromuscular Stimulators
- Magnetic Stimulators
- Electromagnetic Stimulators
- Stimulation Electrodes
- Electromyograph (EMG) Biofeedback Device
- Electromyograph (EMG) Biofeedback and Neuromuscular Stimulator
- Shortwave Therapy Devices
- Laser Therapy Devices

Notified Body

TÜV Rheinland LGA Products GmbH TÜVRheinland® Zertifizierungsstelle

Date: 2020-08-03

Dipl.-Ing. W. Hsu

TÜVRheinland®

Doc. 2/2, Rev.0

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Attachment to Certificate
Registration No.: HD 60147882 0001
Report No.: 17057653 014

Manufacturer: Shenzhen Dongdixin Technology Co., Ltd.
Floor 1-2, No.3 Building,
Fanshen Xusheng Industrial Estate
Xilixiaobaimang
518108 Nanshan District, Shenzhen
P.R. China

Sites included:

Block A, 5th floor, FUHUA Technic Building, NO.9116 BEIHUAN Road, Nanshan District, Shenzhen 518057, China

Floor 1, No.2 Building, Xinjianxing Industrial Estate, Yangguang 2nd Road, Nanshan District, Shenzhen 518108, China

Notified Body

Dipl.-Ing. W. Hsu

TÜV Rheinland LGA Products GmbH TÜVRheinland® Zertifizierungsstelle

Date: 2020-08-03

Add value.
Inspire trust.

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

Shenzhen Dongdixin Technology Co., Ltd.
Floor 1-2, No.3 Building
Fanshen Xusheng Industrial Estate Xilixiaobaimang
Nanshan District
518108 Shenzhen
PEOPLE'S REPUBLIC OF CHINA

Your reference/letter of	Our reference/name	E-mail	Tel. extension	Date	Page
047384	GZ2350301_CL	Emerson.Huang@tuvsud.com	+86 20 3817 0641	2024-04-29	1 of 6

TÜV SÜD Product Service GmbH
Confirmation Letter

CL 047384 0015 Rev. 00

Reference: 713297085 | 713302742 | GZ2350301_CL

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-000009429

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.

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)

The issuance of the first confirmation letter is free of charge. We reserve the right to invoice further copies, amendments and / or changes of the confirmation letter according to effort.

For confirmation letter validity see: www.tuvsud.com/ps-cert?q=cert:CL 047384 0015 Rev. 00

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

On behalf of the Notified Body TÜV SÜD Product Service GmbH,
2024-05-10

TÜV SÜD Product Service GmbH
Medical and Health Services

Emerson Huang 2024.05.10

Emerson Huang
Conformity Assessment Responsible (CARE)

TÜV SÜD Product Service GmbH
Medical and Health Services

Fatlume Bahtiri
2024.05.10 11:21:58
+02'00'

Fatlume Bahtiri
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:

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 Thermometers **Basic UDI-DI:** 69264087TH001PN 69264087TH002PQ 69264087TH003PS	☐ 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	☒ N/A or ☐ Identification of the corresponding device under MDD/AIMDD Individual Article number:	☒ Certification as follows: Certificate #: HD 60147882 0001 NB #0197 (TÜV Rheinland) NOTE: TÜV Süd takes over responsibility for appropriate surveillance on 2024-05-25.
Electrical Stimulators **Basic UDI-DI:** 69264087LT001PJ 69264087LT002PL 69264087LT003PN	☐ 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	☒ N/A or ☐ Identification of the corresponding device under MDD/AIMDD Individual Article number:	☒ Certification as follows: Certificate #: HD 60147882 0001 NB #0197 (TÜV Rheinland) NOTE: TÜV Süd takes over responsibility for appropriate surveillance on 2024-05-25.
Electrical Neuromuscular Incontinence Stimulators **Basic UDI-DI:** 69264087LT004PQ	☐ 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	☒ N/A or ☐ Identification of the corresponding device under MDD/AIMDD Individual Article number:	☒ Certification as follows: Certificate #: HD 60147882 0001 NB #0197 (TÜV Rheinland) NOTE: TÜV Süd takes over responsibility for appropriate surveillance on 2024-05-25.

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
Electrical Acupuncture Stimulators **Basic UDI-DI:** 69264087NT001Q8	☐ 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	☒ N/A or ☐ Identification of the corresponding device under MDD/AIMDD Individual Article number:	☒ Certification as follows: Certificate #: HD 60147882 0001 NB #0197 (TÜV Rheinland) NOTE: TÜV Süd takes over responsibility for appropriate surveillance on 2024-05-25.
Electromagentic Stimulators **Basic UDI-DI:** 69264087MA001KQ	☐ 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	☒ N/A or ☐ Identification of the corresponding device under MDD/AIMDD Individual Article number:	☒ Certification as follows: Certificate #: HD 60147882 0001 NB #0197 (TÜV Rheinland) NOTE: TÜV Süd takes over responsibility for appropriate surveillance on 2024-05-25.
Electrotherapy Devices **Basic UDI-DI:** 69264087MT001PV 69264087MT004Q3	☐ 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	☒ N/A or ☐ Identification of the corresponding device under MDD/AIMDD Individual Article number:	☒ Certification as follows: Certificate #: HD 60147882 0001 NB #0197 (TÜV Rheinland) NOTE: TÜV Süd takes over responsibility for appropriate surveillance on 2024-05-25.

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
Shortwave Therapy Devices **Basic UDI-DI:** 69264087ST001RX	☐ 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	☒ N/A or ☐ Identification of the corresponding device under MDD/AIMDD Individual Article number:	☒ Certification as follows: Certificate #: HD 60147882 0001 NB #0197 (TÜV Rheinland) NOTE: TÜV Süd takes over responsibility for appropriate surveillance on 2024-05-25.
Ultrasound Therapy and Electrotherapy Devices **Basic UDI-DI:** 69264087CT001LF 69264087CT002LH 69264087CT003LK	☐ 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	☒ N/A or ☐ Identification of the corresponding device under MDD/AIMDD Individual Article number:	☒ Certification as follows: Certificate #: HD 60147882 0001 NB #0197 (TÜV Rheinland) NOTE: TÜV Süd takes over responsibility for appropriate surveillance on 2024-05-25.
Ultrasound Therapy Devices **Basic UDI-DI:** 69264087UT001SM 69264087UT002SP	☐ 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	☒ N/A or ☐ Identification of the corresponding device under MDD/AIMDD Individual Article number:	☒ Certification as follows: Certificate #: HD 60147882 0001 NB #0197 (TÜV Rheinland) NOTE: TÜV Süd takes over responsibility for appropriate surveillance on 2024-05-25.

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
Laser Therapy Devices **Basic UDI-DI:** 69264087LS001PB	☐ 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	☒ N/A or ☐ Identification of the corresponding device under MDD/AIMDD Individual Article number:	☒ Certification as follows: Certificate #: HD 60147882 0001 NB #0197 (TÜV Rheinland) NOTE: TÜV Süd takes over responsibility for appropriate surveillance on 2024-05-25.

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
Not applicable	☒ N/A	☒ N/A	☒ N/A

Confirmation Letter Version History

Date	TÜV SÜD Product Service GmbH internal reference traceable to each version of the letter	Action
2024-05-10	GZ2350301_CL	Initial issue