

Certificate

Quality Management System
EN ISO 13485:2016

Registration No.: SX 2031190-1

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

Scope: Design and Development, Manufacture and Distribution of Clinical Electronic Thermometers, Infrared Ear/Forehead Thermometers, Infrared Ear Thermometers, Infrared Forehead Thermometers, Nerve and Muscle Stimulators, Transcutaneous Electrical Nerve Stimulators, Electrical Muscle Stimulators, Electrical Acupuncture Stimulators, Electrical Neuromuscular Incontinence Stimulators, Ultrasound Physical Therapy Devices, Ultrasound and Electrical Neuromuscular Stimulators, Magnetic Stimulators, Electromagnetic Stimulator, Stimulation Electrodes, Electromyograph (EMG) Biofeedback Device, Electromyograph (EMG) Biofeedback and Neuromuscular Stimulator, Shortwave therapy devices, Laser therapy devices, Medium-wave diathermy treatment system (TECAR(Therapy with capacitive and resistive electrodes) Therapy device), Electromechanical orthopaedic extracorporeal shock wave therapy system

The Certification Body of TÜV Rheinland LGA Products GmbH certifies that the organization has established and applies a quality management system for medical devices.
Proof has been furnished that the requirements specified in the abovementioned standard are fulfilled. The quality management system is subject to yearly surveillance.

Report No.: 10920352-100
Effective date: 2022-06-22
Expiry date: 2025-06-21
Issue date: 2022-06-08



Dipl.-Ing. W. Hsu
TÜV Rheinland LGA Products GmbH
Tillystraße 2 · 90431 Nürnberg · Germany

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 Xilixiaobaimang 518108 Nanshan District,
 Shenzhen
 P.R. China

The scope of certification also covers the following:

No.	Facility	Scope
/01	c/o Shenzhen Dongdixin Technology Co., Ltd. Floor 1-2, No.3 Building, Fanshen Xusheng Industrial Estate Xilixiaobaimang 518108 Nanshan District, Shenzhen P.R. China	License holder; Manufacture of Clinical Electronic Thermometers, Infrared Ear/Forehead Thermometers, Infrared Ear Thermometers, Infrared Forehead Thermometers, Nerve and Muscle Stimulators, Transcutaneous Electrical Nerve Stimulators, Electrical Muscle Stimulators, Electrical Acupuncture Stimulators, Electrical Neuromuscular Incontinence Stimulators, Ultrasound Physical Therapy Devices, Ultrasound and Electrical Neuromuscular Stimulators, Magnetic Stimulators, Electromagnetic Stimulator, Stimulation Electrodes, Electromyograph (EMG) Biofeedback Device, Electromyograph (EMG) Biofeedback and Neuromuscular Stimulator, Shortwave therapy devices, Laser therapy devices, Medium-wave diathermy treatment system (TECAR(Therapy with capacitive and resistive electrodes) Therapy device), Electromechanical orthopaedic extracorporeal shock wave therapy system

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Shenzhen
P.R. China

The scope of certification also covers the following:

/02	c/o Shenzhen Dongdixin Technology Co., Ltd. Floor 3-5, No.3 Building, Fanshen Xusheng Industrial Estate Xilixiaobaimang 518108 Nanshan District, Shenzhen P.R. China	Manufacture of Clinical Electronic Thermometers, Infrared Ear/Forehead Thermometers, Infrared Ear Thermometers, Infrared Forehead Thermometers, Nerve and Muscle Stimulators, Transcutaneous Electrical Nerve Stimulators, Electrical Muscle Stimulators, Electrical Acupuncture Stimulators, Electrical Neuromuscular Incontinence Stimulators, Ultrasound Physical Therapy Devices, Ultrasound and Electrical Neuromuscular Stimulators, Magnetic Stimulators, Electromagnetic Stimulator, Stimulation Electrodes, Electromyograph (EMG) Biofeedback Device, Electromyograph (EMG) Biofeedback and Neuromuscular Stimulator, Shortwave therapy devices, Laser therapy devices, Medium-wave diathermy treatment system (TECAR(Therapy with capacitive and resistive electrodes) Therapy device), Electromechanical orthopaedic extracorporeal shock wave therapy system
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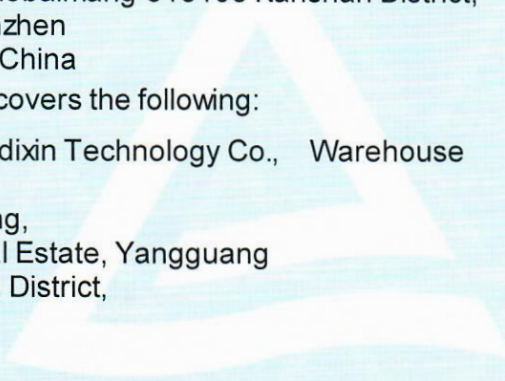
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Organization: Shenzhen Dongdixin Technology Co., Ltd.
Floor 1-2, No.3 Building,
Fanshen Xusheng Industrial Estate
Xilixiaobaimang 518108 Nanshan District,
Shenzhen
P.R. China

The scope of certification also covers the following:

/03 c/o Shenzhen Dongdixin Technology Co., Warehouse
Ltd.
Floor 1, No.2 Building,
Xinjianxing Industrial Estate, Yangguang
2nd Road, Nanshan District,
Shenzhen 518108,
P.R. China


TÜVRheinland

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A handwritten signature in blue ink, likely belonging to Dipl.-Ing. W. Hsu.

Dipl.-Ing. W. Hsu
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Xilixiaobaimang 518108 Nanshan District,
Shenzhen
P.R. China

The scope of certification also covers the following:

/04	c/o Shenzhen Dongdixin Technology Co., Ltd. Block A, 5th floor, FUHUA Technic Building, NO. 9116 BEIHUAN Road Nanshan District, Shenzhen 518057, P.R. China	Design and Development, Distribution of Clinical Electronic Thermometers, Infrared Ear/Forehead Thermometers, Infrared Ear Thermometers, Infrared Forehead Thermometers, Nerve and Muscle Stimulators, Transcutaneous Electrical Nerve Stimulators, Electrical Muscle Stimulators, Electrical Acupuncture Stimulators, Electrical Neuromuscular Incontinence Stimulators, Ultrasound Physical Therapy Devices, Ultrasound and Electrical Neuromuscular Stimulators, Magnetic Stimulators, Electromagnetic Stimulator, Stimulation Electrodes, Electromyograph (EMG) Biofeedback Device, Electromyograph (EMG) Biofeedback and Neuromuscular Stimulator, Shortwave therapy devices, Laser therapy devices, Medium-wave diathermy treatment system (TECAR(Therapy with capacitive and resistive electrodes) Therapy device), Electromechanical orthopaedic extracorporeal shock wave therapy system
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