



INTERNATIONAL
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CERTIFICATE OF ACCREDITATION

This is to attest

HEFEI SUNGO MEDICAL TECHNOLOGY CO., LTD.

UNIT 03, BUILDING 7, WANMAO INDUSTRIAL PARK, PENGYI ROAD, ZIPENG TOWN, FEIXI COUNTY
HEFEI CITY, 231201, CHINA

Testing Laboratory TL-1119

has met the requirements of AC89, *IAS Accreditation Criteria for Testing Laboratories*, and has demonstrated compliance with ISO/IEC Standard 17025:2017, *General requirements for the competence of testing and calibration laboratories*. This organization is accredited to provide the services specified in the scope of accreditation.

Effective Date June 4, 2026



International Accreditation Service
Issued under the authority of IAS management

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International Accreditation Service, Inc.

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HEFEI SUNGO MEDICAL TECHNOLOGY CO., LTD.

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Contact Name Gan Haixiao

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Accredited to ISO/IEC 17025:2017

Effective Date June 4, 2026

Electrical/Mechanical/Physical Testing	
ANSI/RESNA WC-1	American National Standard for Wheelchairs - Volume 1: Requirements and Test Methods for Wheelchairs (including Scooters)
ANSI/RESNA WC-2	American National Standard for Wheelchairs - Volume 2: Additional Requirements for Wheelchairs (including Scooters) with Electrical Systems
ASTM D4169	Standard Practice for Performance Testing of Shipping Containers and Systems (Except for Schedule G, H)
ASTM F1980	Standard Guide for Accelerated Aging of Sterile Barrier Systems and Medical Devices
CISPR 11	Industrial, scientific and medical equipment - Radio-frequency disturbance characteristics - Limits and methods of measurement
EN 12183	Manual wheelchairs - Requirements and test methods except for 5.6 Biocompatibility and toxicity
EN 12184	Electrically powered wheelchairs, scooters and their chargers - Requirements and test methods except for 6.6 Biocompatibility and toxicity, 12.3.1
EN 60601-1	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
EN 60601-1-11	Medical electrical equipment - Part 1-11: General requirements for basic safety and essential performance - Collateral Standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment
EN 60601-1-2	Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests
EN 60601-1-8	Medical electrical equipment - Part 1-8: General requirements for basic safety and essential performance - Collateral Standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems
EN 61000-3-3	Electromagnetic compatibility (EMC) - Part 3-3: Limits - Limitation of voltage changes, voltage fluctuations and flicker in public low-voltage supply systems,

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	for equipment with rated current ≤ 16 A per phase and not subject to conditional connection
EN 61000-4-2	Electromagnetic compatibility (EMC) - Part 4-2: Testing and measurement techniques - Electrostatic discharge immunity test
EN 61000-4-39	Electromagnetic compatibility (EMC) - Part 4-39: Testing and measurement techniques - Radiated fields in close proximity - Immunity test
EN 61000-4-4	Electromagnetic compatibility (EMC) - Part 4-4: Testing and measurement techniques - Electrical fast transient/burst immunity test
EN 61000-4-5	Electromagnetic compatibility (EMC) - Part 4-5: Testing and measurement techniques - Surge immunity test
EN 61000-4-6	Electromagnetic compatibility (EMC) - Part 4-6: Testing and measurement techniques - Immunity to conducted disturbances, induced by radio-frequency fields
EN 61000-4-8	Electromagnetic compatibility (EMC) - Part 4-8: Testing and measurement techniques - Power frequency magnetic field immunity test
EN IEC 61000-3-2	Electromagnetic compatibility (EMC) - Part 3-2: Limits - Limits for harmonic current emissions (equipment input current ≤ 16 A per phase)
EN IEC 61000-4-11	Electromagnetic compatibility (EMC) - Part 4-11: Testing and measurement techniques - Voltage dips, short interruptions and voltage variations immunity tests for equipment with input current up to 16 A per phase
EN IEC 61000-4-2	Electromagnetic compatibility (EMC) - Part 4-2: Testing and measurement techniques - Electrostatic discharge immunity test
EN IEC 61000-4-3	Electromagnetic compatibility (EMC) - Part 4-3: Testing and measurement techniques - Radiated, radio-frequency, electromagnetic field immunity test
EN IEC 61000-4-6	Electromagnetic compatibility (EMC) - Part 4-6: Testing and measurement techniques - Immunity to conducted disturbances, induced by radio-frequency fields
EN IEC 61326-2-6	Electrical equipment for measurement, control and laboratory use - EMC requirements - Part 2-6: Particular requirements - In vitro diagnostic (IVD) medical electrical equipment
EN ISO 21856	Assistive products - General requirements and test methods (ISO 21856:2022) (except for 4.3 Clinical evaluation, 5.2 Flammability, 5.3 Biocompatibility and toxicity, 8.3 Electrically heated blankets, pads and similar flexible heating appliances, 11 Sterility, 17.4 Requirements and test method for tips)
EN ISO 80601-2-69	Medical electrical equipment - Part 2-69: Particular requirements for the basic safety and essential performance of oxygen concentrator equipment
GB 17625.1	Electromagnetic compatibility - Limits - Part 1: Limits for harmonic current emissions (equipment input current ≤ 16 A per phase)

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GB 4824	Industrial, scientific and medical equipment - Radio-frequency disturbance characteristics - Limits and methods of measurement
GB 9706.1	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
GB/T 14728.1	Assistive products for walking manipulated by both arms - Requirements and test methods - Part 1: Walking frames. add except for 7.3
GB/T 14728.2	Assistive products for walking manipulated by both arms - Requirements and test methods - Part 2: Rollators except for 7.3
GB/T 14728.3	Walking aids manipulated by both arms - Requirements and test methods - Part 3: Walking tables add except for 4.9 Materials and finish
GB/T 17625.2	Electromagnetic compatibility (EMC) - Limits - Limitation of voltage changes, voltage fluctuations and flicker in public low-voltage supply systems, for equipment with rated current ≤ 16 A per phase and not subject to conditional connection
GB/T 17626.11	Electromagnetic compatibility - Testing and measurement techniques - Part 11: Voltage dips, short interruptions and voltage variations immunity tests for equipment with input current up to 16 A per phase
GB/T 17626.2	Electromagnetic compatibility - Testing and measurement techniques - Electrostatic discharge immunity test
GB/T 17626.3	Electromagnetic compatibility - Testing and measurement techniques - Part 3: Radiated, radio-frequency, electromagnetic field immunity test
GB/T 17626.39	Electromagnetic compatibility - Testing and measurement techniques - Part 39: Radiated fields in close proximity - Immunity test
GB/T 17626.4	Electromagnetic compatibility - Testing and measurement techniques - Electrical fast transient/burst immunity test
GB/T 17626.5	Electromagnetic compatibility - Testing and measurement techniques - Surge immunity test
GB/T 17626.6	Electromagnetic compatibility - Testing and measurement techniques - Immunity to conducted disturbances, induced by radio-frequency fields
GB/T 17626.8	Electromagnetic compatibility - Testing and measurement techniques - Power frequency magnetic field immunity test
GB/T 18029.1	Wheelchairs—Part 1: Determination of static stability
GB/T 18029.13	Wheelchairs - Part 13: Determination of coefficient of friction of test surfaces
GB/T 18029.14	Wheelchairs—Part 14: Power and control systems for electrically powered wheelchairs and Scooter - Requirements and test methods

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GB/T 18029.15	Wheelchairs --Part 15: Requirement for information disclosure, documentation and labelling
GB/T 18029.2	Wheelchairs—Part 2: Determination of dynamic stability of electrically powered wheelchairs
GB/T 18029.21	Wheelchairs - Part 21: Requirements and test methods for electromagnetic compatibility of electrically powered wheelchairs and scooters, and battery chargers
GB/T 18029.22	Wheelchairs—Part 22: Set-up procedures
GB/T 18029.25	Wheelchairs—Part 25: Batteries and chargers for powered wheelchairs
GB/T 18029.30	Wheelchairs - Part 30: Wheelchairs for changing occupant posture - Test methods and requirements
GB/T 18029.6	Wheelchairs—Part 6: Determination of maximum speed, acceleration and deceleration of electric wheelchairs
GB/T 18029.7	Wheelchairs—Part 7: Measurement of seating and wheel dimensions
GB/T 18029.8	Wheelchairs—Part 8: Requirements and test methods for static, impact and fatigue strengths
GB/T 18268.26	Electrical equipment for measurement, control and laboratory use - EMC requirements - Part 26: Particular requirements - In vitro diagnostic (IVD) medical equipment
GB/T 19545.1	Walking aids manipulated by one arm - Requirements and test methods - Part 1: Elbow crutches
GB/T 19545.2	Walking aids manipulated by one arm - Requirements and test methods - Part 2: Axillary crutches
GB/T 19545.4	Walking aids manipulated by one arm - Requirements and test methods - Part 4: Walking sticks with three or more legs except for 4.4 Materials
GB/T 24434	Commode chairs
GB/T 43386	Assistive products for personal hygiene that support users - Requirements and test methods (except for 4.3 Clinical evaluation and investigation, 5.3 Biocompatibility and toxicity)
GB/Z 18029.10	Wheelchairs—Part 10: Determination of obstacle-climbing ability of electrically powered wheelchairs
GB/Z 18029.11	Wheelchairs—Part 11: Test dummies
GB/Z 18029.16	Wheelchairs—Part 16: Resistance to ignition of postural support devices
GB/Z 18029.3	Wheelchairs—Part 3: Determination of effectiveness of brakes

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GB/Z 18029.4	Wheelchairs—Part 4: Energy consumption of electric wheelchairs and scooters for determination of theoretical distance range
GB/Z 18029.5	Wheelchairs —Part 5: Determination of dimensions, mass and maneuvering space
GB/Z 18029.9	Wheelchairs—Part 9: Climatic tests for electric wheelchairs
IEC 60601-1	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
IEC 60601-1-11	Medical electrical equipment - Part 1-11: General requirements for basic safety and essential performance - Collateral Standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment
IEC 60601-1-2	Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests
IEC 60601-1-8	Medical electrical equipment - Part 1-8: General requirements for basic safety and essential performance - Collateral Standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems
IEC 61000-3-2	Electromagnetic compatibility (EMC) - Part 3-2: Limits - Limits for harmonic current emissions (equipment input current ≤ 16 A per phase)
IEC 61000-3-3	Electromagnetic compatibility (EMC) - Part 3-3: Limits - Limitation of voltage changes, voltage fluctuations and flicker in public low-voltage supply systems, for equipment with rated current ≤ 16 A per phase and not subject to conditional connection
IEC 61000-4-11	Electromagnetic compatibility (EMC) - Part 4-11: Testing and measurement techniques - Voltage dips, short interruptions and voltage variations immunity tests for equipment with input current up to 16 A per phase
IEC 61000-4-2	Electromagnetic compatibility (EMC) - Part 4-2: Testing and measurement techniques - Electrostatic discharge immunity test
IEC 61000-4-3	Electromagnetic compatibility (EMC) - Part 4-3: Testing and measurement techniques - Radiated, radio-frequency, electromagnetic field immunity test
IEC 61000-4-39	Electromagnetic compatibility (EMC) - Part 4-39: Testing and measurement techniques - Radiated fields in close proximity - Immunity test
IEC 61000-4-4	Electromagnetic compatibility (EMC) - Part 4-4: Testing and measurement techniques - Electrical fast transient/burst immunity test
IEC 61000-4-5	Electromagnetic compatibility (EMC) - Part 4-5: Testing and measurement techniques - Surge immunity test

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IEC 61000-4-6	Electromagnetic compatibility (EMC) - Part 4-6: Testing and measurement techniques - Immunity to conducted disturbances, induced by radio-frequency fields
IEC 61000-4-8	Electromagnetic compatibility (EMC) - Part 4-8: Testing and measurement techniques - Power frequency magnetic field immunity test
IEC 61326-2-6	Electrical equipment for measurement, control and laboratory use - EMC requirements - Part 2-6: Particular requirements - In vitro diagnostic (IVD) medical electrical equipment
IEC TS 60601-4-2	Medical electrical equipment - Part 4-2: Guidance and interpretation - Electromagnetic immunity: performance of medical electrical equipment and medical electrical systems
IEEE/ANSI C63.18	American National Standard Recommended Practice for an On-Site, Ad Hoc Test Method for Estimating Electromagnetic Immunity of Medical Devices to Radiated Radio-Frequency (RF) Emissions from RF Transmitters
ISO 11199-1	Assistive products for walking manipulated by both arms - Requirements and test methods - Part 1: Walking frames except for 7.3 Biocompatibility and toxicity
ISO 11199-2	Assistive products for walking manipulated by both arms - Requirements and test methods - Part 2: Rollators except for 7.3 Biocompatibility and toxicity
ISO 11199-3	Walking aids manipulated by both arms - Requirements and test methods - Part 3: Walking tables except for 4.9 Materials and finish
ISO 11334-1	Assistive products for walking manipulated by one arm - Requirements and test methods - Part 1: Elbow crutches
ISO 11334-4	Assistive products for walking, manipulated by one arm - Requirements and test methods - Part 4: Walking sticks with three or more legs except for 4.4 Materials
ISO 16840-10	Wheelchair seating — Part 10: Resistance to ignition of postural support devices - Requirements and test method
ISO 17966	Assistive products for personal hygiene that support users - Requirements and test methods (except for 4.3 Clinical evaluation and investigation, 5.3 Biocompatibility and toxicity)
ISO 21856	Assistive products - General requirements and test methods (except for 4.3 Clinical evaluation, 5.2 Flammability, 5.3 Biocompatibility and toxicity, 8.3 Electrically heated blankets, pads and similar flexible heating appliances, 11 Sterility, 17.4 Requirements and test method for tips)
ISO 7176-1	Wheelchairs - Part 1: Determination of static stability
ISO 7176-10	Wheelchairs - Part 10: Determination of obstacle-climbing ability of electrically powered wheelchairs
ISO 7176-11	Wheelchairs - Part 11: Test dummies
ISO 7176-13	Wheelchairs - Part 13: Determination of coefficient of friction of test surfaces

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ISO 7176-14	Wheelchairs - Part 14: Power and control systems for electrically powered wheelchairs and scooters - Requirements and test methods
ISO 7176-15	Wheelchairs - Part 15: Requirements for information disclosure, documentation and labelling
ISO 7176-16	Wheelchairs - Part 16: Resistance to ignition of postural support devices
ISO 7176-2	Wheelchairs - Part 2: Determination of dynamic stability of electrically powered wheelchairs
ISO 7176-21	Wheelchairs - Part 21: Requirements and test methods for electromagnetic compatibility of electrically powered wheelchairs and scooters, and battery chargers
ISO 7176-22	Wheelchairs - Part 22: Set-up procedures
ISO 7176-25	Wheelchairs - Part 25: Lead-acid batteries and chargers for powered wheelchairs - Requirements and test methods
ISO 7176-3	Wheelchairs - Part 3: Determination of effectiveness of brakes
ISO 7176-30	Wheelchairs - Part 30: Wheelchairs for changing occupant posture - Test methods and requirements
ISO 7176-31	Wheelchairs - Part 31: Lithium-ion battery systems and chargers for powered wheelchairs - Requirements and test methods
ISO 7176-4	Wheelchairs - Part 4: Energy consumption of electric wheelchairs and scooters for determination of theoretical distance range
ISO 7176-5	Wheelchairs - Part 5: Determination of dimensions, mass and manoeuvring space
ISO 7176-6	Wheelchairs - Part 6: Determination of maximum speed of electrically powered wheelchairs
ISO 7176-7	Wheelchairs - Part 7: Measurement of seating and wheel dimensions
ISO 7176-8	Wheelchairs - Part 8: Requirements and test methods for static, impact and fatigue strengths
ISO 7176-9	Wheelchairs - Part 9: Climatic tests for electric wheelchairs
ISO 80601-2-69	Medical electrical equipment - Part 2-69: Particular requirements for the basic safety and essential performance of oxygen concentrator equipment
ISO 9227	Corrosion tests in artificial atmospheres - Salt spray tests
ISTA 2A	ISTA 2 Series Partial Simulation Performance Test Procedure: Packaged-Products 150lb(68kg) or less (Except for Incline Impact test and Horizontal Impact test)
ISTA 3A	ISTA 3 Series General Simulation Performance Test Procedure: Packaged-Products for Parcel Delivery System Shipment 70 kg (150 lb) or Less (except for Random vibration under low pressure)
MZ/T 119	Assistive products for showering-shower chairs except for 7 Materials

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YY 9706.102	Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic compatibility - Requirements and tests
YY 9706.108	Medical electrical equipment - Part 1-8: General requirements for basic safety and essential performance - Collateral standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems
YY 9706.111	Medical electrical equipment - Part 1-11: General requirements for basic safety and essential performance - Collateral Standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment
YY 9706.269	Medical electrical equipment - Part 2-69: Particular requirements for basic safety and essential performance of oxygen concentrator equipment
YY/T 0681.1	Test methods for sterile medical device package—Part 1: Test guide for accelerated aging
YY/T 0681.15	Test methods for sterile medical device package—Part 15: Performance testing of shipping containers and systems

