



CERTIFICATE OF ACCREDITATION

This is to attest

ZHONG TIAN HONG TU INTERNATIONAL CERTIFICATION CO., LTD.

UNIT 906/908, BLOCK 3, TIAN XIA YI JIA HUA FU, GAO QIAO STREET
YUHUA DESTRIC, CHANGSHA, HUNAN 410001
PEOPLE'S REPUBLIC OF CHINA

Management System Certification Body MSCB-315

has met the requirements of AC477, IAS Accreditation Criteria for Management System Certification Bodies, and has demonstrated compliance with the ISO/IEC 17021-1:2015 Standard, Conformity assessment – Requirements for bodies providing audit and certification of management systems. This organization is accredited to provide the services specified in the scope of accreditation.

Effective Date February 9, 2025

(Valid as per IAS 4-year accreditation cycle subject to periodic assessments and satisfactory closure of findings)

Accredited Since September 7, 2023



International Accreditation Service
Issued under the authority of IAS management

Visit www.iasonline.org for current accreditation information.

SCOPE OF ACCREDITATION

International Accreditation Service, Inc.

3060 Saturn Street, Suite 100, Brea, California 92821, U.S.A. | www.iasonline.org

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PEOPLE'S REPUBLIC OF CHINA

Management System Certification Body MSCB-315

Contact Name Haijiang Li

Contact Phone +86-18908471766

Accredited to ISO/IEC 17021-1:2015

Effective Date February 9, 2025

Discipline of Certification:	Quality Management Systems
Accredited To/Additional Level 4 Standard:	ISO/IEC 17021-3:2017
Certification Standard:	ISO 9001:2015/ GB/T 19001-2016
Certification Scheme:	N/A
Certification Sectors	
12: Chemicals, Chemical Products and Fibres 14: Rubber and Plastic Products 15: Non-metallic Mineral Products 16: Concrete, Cement, Lime, Plaster, etc. 17: Basic Metals and Fabricated Metal Products 18: Machinery and Equipment 19: Electrical and Optical Equipment	22: Other Transport Equipment 23: Manufacturing Not Elsewhere Classified 29: Wholesale and Retail Trade; Repair of Motor Vehicles, Motorcycles and Personal and Household Goods 33: Information Technology 34: Engineering Services

Discipline of Certification:	Environmental Management Systems
Accredited To/Additional Level 4 Standard:	ISO/IEC 17021-2:2016
Certification Standard:	ISO 14001:2015/ GB/T 24001-2016
Certification Scheme:	N/A
Certification Sectors	
12: Chemicals, Chemical Products and Fibres 14: Rubber and Plastic Products 15: Non-metallic Mineral Products 16: Concrete, Cement, Lime, Plaster, etc. 17: Basic Metals and Fabricated Metal Products 18: Machinery and Equipment 19: Electrical and Optical Equipment	22: Other Transport Equipment 23: Manufacturing Not Elsewhere Classified 29: Wholesale and Retail Trade; Repair of Motor Vehicles, Motorcycles and Personal and Household Goods 33: Information Technology 34: Engineering Services

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IAF MLA Signatory for Management System
(QMS, EMS, ISMS, FSMS, EnMS, MDQMS, OHSMS)

SCOPE OF ACCREDITATION

International Accreditation Service, Inc.

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Discipline of Certification:	<i>Occupational Health and Safety Management Systems</i>
Accredited To/Additional Level 4 Standard:	<i>ISO/IEC TS 17021-10:2018</i>
Certification Standard:	<i>ISO 45001:2018/ GB/T 45001-2020</i>
Certification Scheme:	<i>N/A</i>
Certification Sectors	
12: Chemicals, Chemical Products and Fibres 14: Rubber and Plastic Products 15: Non-metallic Mineral Products 16: Concrete, Cement, Lime, Plaster, etc. 17: Basic Metals and Fabricated Metal Products 18: Machinery and Equipment 19: Electrical and Optical Equipment	22: Other Transport Equipment 23: Manufacturing Not Elsewhere Classified 29: Wholesale and Retail Trade; Repair of Motor Vehicles, Motorcycles and Personal and Household Goods 33: Information Technology 34: Engineering Services

SCOPE OF ACCREDITATION

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Discipline of Certification:	<i>Medical Device Quality Management Systems</i>
Certification Standard:	<i>ISO 13485:2016/GB/T 42061-2022</i>
Certification Scheme:	<i>N/A</i>
Main Technical Areas/Technical Areas	
Table A.1.1 – Non-Active Medical Devices	General non-active, non-implantable medical devices
	Non-active implants
	Devices for wound care
	Non-active medical devices other than specified above
Table A.1.2 – Active (Non-Implantable) Medical Devices	Devices for imaging
	Monitoring devices
	Devices for radiation therapy and thermo therapy
	Active (non-implantable) medical devices other than specified above
Table A1.6 – Devices Incorporating/Utilizing Specific Substances/Technologies	Medical devices incorporating medicinal substances
	Medical devices utilizing micromechanics
	Medical devices utilizing nanomaterials
	Medical devices utilizing biological active coatings and/or materials or being wholly or mainly absorbed
Table A1.7 – Parts and Services	Raw materials
	Components
	Subassemblies
	Calibration services
	Distribution services
	Maintenance services
	Transportation services
	Other services

Note: The above scope of accreditation is based on the statistical nomenclature for economic activities NACE rev. 2 and as recommended by the current version of IAF ID 1.

The scope of accreditation represents broad classifications granted by IAS on the basis of the management system certification processes demonstrated by the certification body (CB). Accreditation is based on the competence and ability to effectively apply the requirements of the relevant certification standards listed in the CB's scope of accreditation. IAS accreditation entails review of the CB's own management system, on-site assessment of the CB's certification processes, review of CB's access to expertise including onsite observation of the CB when conducting certification audits at client sites. Under the conditions of accreditation, the CB is obligated to use equivalent certification practices covering the specific scopes as listed for all clients and as demonstrated during the accreditation process. Accreditation does not cover certification in areas outside the scope of this accreditation certificate. Accreditation does not imply endorsement of the products or the design or performance characteristics of products certified by the CB.

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Type of entity	Company name	Address (Street City, Country)	Contact information
CB Key Location	N/A	N/A	N/A
CB Location (No Key Activities)	N/A	N/A	N/A
Subcontractor Key Location	N/A	N/A	N/A
Subcontractor (No Key Activities)	N/A	N/A	N/A

The above table lists any entities performing work on behalf of the accredited MSCB (See IAF MD23:2018, and IAS/MSCB/031 for information regarding types of activities per entity). Types of entities and their descriptions are as follows (please contact IAS should further clarification be required):

CB Key Location: Entities performing and/or managing key management system certification activities, on behalf of accredited certification bodies, which are wholly or partly owned or employed by the CB.

CB Location (No Key Activities): Entities performing and/or managing processes related to management system activities, on behalf of accredited certification bodies, which are wholly or partly owned or employed by the CB (processes include; marketing, communications, outreach, etc.) This list is not all-inclusive; any activity related to the accredited CBs certification program is applicable.

Subcontractor Key Location: Entities performing and/or managing key management system certification activities, on behalf of accredited certification bodies, which are not wholly or partly owned or employed by the CB.

Subcontractor (No Key Activities): Entities performing and/or managing processes related to management system activities, on behalf of accredited certification bodies, which are not wholly or partly owned or employed by the CB (processes include; marketing, communications, outreach, etc.) This list is not all-inclusive; any activity related to the accredited CBs certification program is applicable.