



CERTIFICATE OF ACCREDITATION

This is to attest

BEIJING HUA GUANG CERTIFICATION OF MEDICAL DEVICES CO., LTD.

5 TH FLOOR, A88, AN DING MEN WAI STREET
DONG CHENG DISTRICT, BEIJING, 100011 CHINA

Management System Certification Body MSCB-377

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 July 24, 2025

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

Accredited Since May 16, 2025



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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DONG CHENG DISTRICT, BEIJING, 100011 CHINA

www.cmdc.com.cn

MSCB-377

Contact Name Wan Zhang

Contact Phone +86-13439008925

Accredited to ISO/IEC 17021-1:2015

Effective Date July 24, 2025

Discipline of Certification:	Medical Device Quality Management Systems
Certification Standard:	ISO 13485:2016 / GB/T 42061-2022
Certification Scheme:	N/A
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 dental devices and accessories
	Non-active medical devices other than specified above
Table A.1.4 - In Vitro Diagnostic Medical Devices	Reagents and reagent products, calibrators, and control materials for: Clinical Chemistry Immunochemistry (Immunology) Haematology/Haemostasis/Immunoematology Microbiology Infectious Immunology Histology/Cytology Genetic Testing
	IVD Instruments and software
	IVD medical devices other than specified above

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 CBs 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.

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

SCOPE OF ACCREDITATION

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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.

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)	CMD (Guangdong) Subsidiary	Room 1303-2, 13th Floor, Building 2, No. 88 Xiangshan Road, Tangjiawan Town, High-tech Zone, Zhuhai City · Guangdong Province, China	Yuan Xixi 8610-13727083549 yuanxx98@163.com
CB Location (No Key Activities)	CMD (Suzhou) Subsidiary	Room 401, 410, 411, Building 1, Yongrong Plaza, High-tech Zone, Suzhou City, China	Li Wei 8610-13615109116 cmdsuzhou@163.com
CB Location (No Key Activities)	CMD (Hangzhou) Subsidiary	2nd Floor, Building 6, No. 86-96, Desheng Road, Gongshu District, Hangzhou City, Zhejiang Province, China	Zou Yi 8610-13905713556 zouyi_hz@126.com
CB Location (No Key Activities)	CMD Jinan Branch Company	Room 1-501, Building 2, GangAo Garden No. 7151, East 2nd Ring Road, Lixia District, Jinan City, Shandong Province, China	Xu Wenrong 8610-13156004993 2276573776@qq.com
CB Location (No Key Activities)	CMD Chongqing Office	Room 917, Building 3, Longhu MOCO, Xinnan Road, Tiangongdian Street, Yubei District, Chongqing City, China	Yang Zhibin 8610-13825650556 cmdchongqing@163.com
CB Location (No Key Activities)	CMD Shanghai Office	Room 711, Building 1, Lane 775, Siping Road, Shanghai, China	Xu Zhiliang 8610-13817722876 cmdshanghai@163.com
CB Location (No Key Activities)	CMD Chengdu Office	Room 1, 7th Floor, Block 1B, Borui Chuangyi Chengdu Building, No. 38 Sanse Road, Jinjiang District, Chengdu City, China	Li Xichang 8610-13648073159 cmdsichuan@163.com
CB Location (No Key Activities)	CMD Shenyang Office	Room 1403, Meibo Building, No. 152-1, Xiaonan Street, Shenhe District, Shenyang City, China	Zhang Liwei 8610-13614004395 cmdshenyang@163.com
CB Location (No Key Activities)	CMD Wuhan Office	Room A603, 6th Floor, Building B9, Factory No. 1, No. 818 Gaoxin Avenue, East Lake High-tech Development Zone, Wuhan, Hubei Province, China	Li Jian 8610-13501246766 13501246766@163.com
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.

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