



CERTIFICATE OF ACCREDITATION

This is to attest that

ICR CO., LTD.

1501, DAERUNG POST TOWER 6TH, 298, BEOTKKOT-RO, GEUMCHEON-GU
SEOUL, 08510, REPUBLIC OF KOREA

Management System Certification Body MSCB-321

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 March 30, 2024

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

Accredited Since March 3, 2023



President

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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www.icrqa.com

MSCB-321

Contact Name Sang-Woo Sim

Contact Phone + 82-10-92319088

Accredited to ISO/IEC 17021-1:2015

Effective Date March 30, 2024

Discipline of Certification:	Quality Management Systems
Accredited To/Additional Level 4 Standard:	ISO/IEC 17021-3:2017
Certification Standard:	ISO 9001:2015
Certification Scheme:	N/A
Certification Sectors	
1: Agriculture, Hunting, Forestry & Fishing 2: Mining and Quarrying 3: Food Products, Beverages and Tobacco 4: Textiles and Textile Products 5: Leather and Leather Products 6: Wood and Wood Products 7: Pulp, Paper and Paper Products 8: Publishing Companies 9: Printing Companies 10: Coke and Refined Petroleum Products 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	20: Shipbuilding 22: Other Transport Equipment 23: Manufacturing Not Elsewhere Classified 24: Recycling 28: Construction 29: Wholesale and Retail Trade; Repair of Motor Vehicles, Motorcycles and Personal and Household Goods 30: Hotels and Restaurants 31: Transport, Storage and Communications 32: Financial Intermediation, Real Estate, Renting 33: Information Technology 34: Engineering Services 35: Other Services 36: Public Administration 37: Education 39: Other Social Services

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SCOPE OF ACCREDITATION

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Discipline of Certification:	<i>Environmental Management Systems</i>
Accredited To/Additional Level 4 Standard:	<i>ISO/IEC 17021-2:2016</i>
Certification Standard:	<i>ISO 14001:2015</i>
Certification Scheme:	<i>N/A</i>
Certification Sectors	
3: Food Products, Beverages and Tobacco 4: Textiles and Textile Products 5: Leather and Leather Products 6: Wood and Wood Products 7: Pulp, Paper and Paper Products 8: Publishing Companies 9: Printing Companies 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 20: Shipbuilding 21: Aerospace	22: Other Transport Equipment 23: Manufacturing Not Elsewhere Classified 24: Recycling 28: Construction 29: Wholesale and Retail Trade; Repair of Motor Vehicles, Motorcycles and Personal and Household Goods 30: Hotels and Restaurants 31: Transport, Storage and Communications 32: Financial Intermediation, Real Estate, Renting 33: Information Technology 34: Engineering Services 35: Other Services 36: Public Administration 37: Education 39: Other Social Services

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</i>
Certification Scheme:	<i>N/A</i>
Certification Sectors	
4: Textiles and Textile Products 5: Leather and Leather Products 6: Wood and Wood Products 7: Pulp, Paper and Paper Products 8: Publishing Companies 9: Printing Companies 10: Coke and Refined Petroleum Products 12: Chemicals, Chemical Products and Fibres 13: Pharmaceuticals 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 24: Recycling 28: Construction 29: Wholesale and Retail Trade; Repair of Motor Vehicles, Motorcycles and Personal and Household Goods 31: Transport, Storage and Communications 32: Financial Intermediation, Real Estate, Renting 33: Information Technology 34: Engineering Services 35: Other Services 36: Public Administration 37: Education 39: Other Social Services

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SCOPE OF ACCREDITATION

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Discipline of Certification:	<i>Medical Device Quality Management Systems</i>
Certification Standard:	<i>ISO 13485:2016</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 dental devices and accessories
	Non-active medical devices other than specified above
Table A.1.2 – Active (Non-Implantable) Medical Devices	General active medical devices
	Devices for imaging
	Monitoring devices
	Devices for radiation therapy and thermo therapy
	Active (non-implantable) medical devices other than specified above
Table A.1.3 - Active Implantable Medical Devices	General active implantable medical devices
	Implantable 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/Immunohematology Microbiology Infectious Immunology Histology/Cytology Genetic Testing
	IVD Instruments and software
	IVD medical devices other than specified above
Table A.1.5 – Sterilization Methods for Medical Devices	Ethylene oxide gas sterilization (EOG)
	Moist heat
	Aseptic processing
	Radiation sterilization (e.g., gamma, x-ray, electron beam)
	Sterilization method other than specified above
Table A.1.7 – Parts and Services	Raw materials
	Components
	Subassemblies
	Calibration services
	Distribution services
	Maintenance services
	Transportation services
	Other services

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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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