



"With IGC, Better Quality and Promising Future."

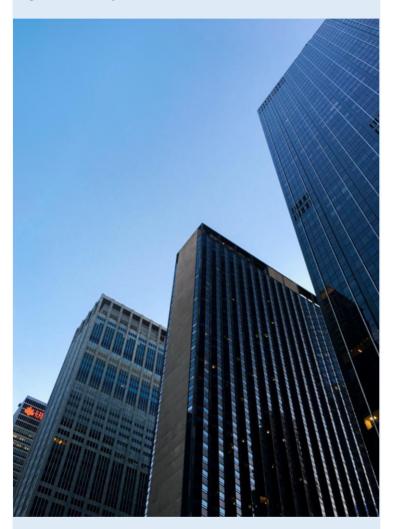


Institute of Global Certification

http://www.igcert.org

IGC

is an internationally accredited certification body that provides system certification, product certification, auditor training, auditor registration, testing and inspection under the concept of customer satisfaction based on global competitiveness



IGC is a competitive system certification body because IGC provides more than 10 standards and training services.

We also provide various business areas such as CE certification, Eurasia certification, and personnel certification.

IGC's competitiveness

- Provide newest information for certification from worldwide networks
- Expertise of Auditor
- · Covering of broad management standards
- Various business
 (Products, Management System, Testing, Personnel Certification)





ISO 9001 Quality Management System

ISO 9001 is an international standard that an organization is capable of continuously improving the quality of its products and services to meet client needs.

The quality innovation and technical development cab be established, and competitiveness can be strengthened by accumulating know-how through documentation and management of records.

ISO 13485 Quality Management System for Medical Devices

ISO 13485 is an international standard based on ISO 9001 with special requirements for medical devices.

It can be applied not only to organization related to medical devices but also to outsourcing organization that provides services such as sterilization, calibration, etc.

Many of buyers request to certify ISO 13485 when the organization exports the medical device to overseas market.

ISO 22000 Food Safety Management System

ISO 22000 is for food safety management system that combines ISO 9001 and HACCP.

ISO 22000 is applicable to all organization related to food industry including equipment production, material packaging, detergents, additives and raw materials.

IGC can certify all food categories.

ISO 14001 Environmental Management System

ISO 14001 is an international standard that evaluated how environmental management for compliance with laws, pollution prevention, management review, correction, etc.) are implementation.

Organization who certified may establish environmentally friendly company image.

ISO 45001 Occupational Health and Safety Management System

ISO 45001 is established to protect personnel resources, prevent economic losses form industrial accidents and disaster, and improve worker productivity.

It can be establishing reliability of employees, as well as, positive image from business partner through obtain ISO 45001 certification.

FSSC 22000 Food Safety System Certification

FSSC 22000 is approved by GFSI(Global Food Safety Initiative) to introduce a food safety certification scheme suitable for whole food industry.

FSSC 22000 combines PRPs(Pre-requisite Programs) and FSSC 22000 additional requirements based on ISO 22000. It is applied to any organization related to food industry.

In addition, IGC is an training provider designated by the FSSC and provides accredited auditor training course.

ISO/IEC 27001 Information Security Management System

ISO/IEC 27001 presents the requirements which need for implementation, maintaining, establishing the information security management system.

The certified organization can objectively demonstrate for ISMS and provides reliability to clients and business partners through ISO/IEC 27001 certification.

ISO/IEC 20000-1 IT-Service Management System

ISO/IEC 20000-1 is for IT-service management system.

ISO/IEC 20000-1 supports to establish design, planning, providing, operating the management system and it can manage systematically and improve the service quality of IT service.

ISO 22301 Business Continuity Management System

ISO 22301 is international standards for providing guidance to sustain the business operations when the business suspends.

The introduction of ISO 22301 enables organizations to implement and operate overall control the incident.

ISO 50001 Energy Management System

ISO 50001 is an international standard that the organizations improve energy performance through systematic energy management.

ISO 50001 enables to reduce greenhouse gas emission, energy costs, and other related environmental impacts and build positive images from clients and business partners.

ISO/IEC 27701 Privacy Information Management System

ISO/IEC 27701 is an extension standard of ISO/IEC 27001 and ISO/IEC 27002 for protecting the privacy information.

The certified organization provides reliability to clients and business partner through Privacy information management system.

ISO 21001 Management System for Educational Organizations

ISO 21001 is for organization providing products and services related to education.

ISO 21001 supports to meet the student's requirements and needs, and provides specific framework for educational organizations that aim to increase student's satisfaction.

ISO 37001 Anti-bribery Management System

ISO 37001 is international standard for preventing bribery and implementing the related polices.

ISO 37001 is established to prevent the critical risks and losses that cause bribery and it improve the reliability to clients and business partner.



ISO 22716 Cosmetics-GMP

ISO 22716 is guideline for cosmetics GMP. Each country has its own cosmetics GMP, and ISO 22716 has been established to addressing these regulatory differences.

The organization can response to the regulation from domestic and abroad, and it enhances export competitiveness through obtaining ISO 22716.

ISO 14155 Clinical Investigation of Medical Device - Good Clinical Practice

ISO 14155 is an international standard that provides guidelines for designing, conducting, reporting the clinical investigation to assess the performance, effectiveness, and safety of medical devices.

ISO 14155 ensures the reliability of clinical investigation data and protects human rights and safety.

ISO 15378 Primary Packaging Material for Medicinal Product-GMP

ISO 15378 is the guideline for primary packaging material for medicinal product.

Primary packaging materials contact with the contents of drug directly, and ISO 15378 is established to prevent drug contamination caused by packaging materials.

ISO 15378 enables organizations to enhance the competitiveness by ensuring high-quality products.



Cosmetics

FDA Cosmetic Registration (VCRP – The Voluntary Cosmetic Registration Program)

The Voluntary Cosmetic Registration Program (VCRP) is a system that registers the manufacturing facilities and ingredients of cosmetics distributed in the United States with the FDA

VCRP can help the entities promote their export activities.

Eurasia EAC Certification

EAC certification or State Registration is required for exporting the cosmetics to Eurasia. A Russian representative is required and test reports issued by laboratories in Eurasia are only accepted.

General Cosmetics

EAC DoC (TR CU 009/2011 On safety of cosmetics and perfumes)

Functional Cosmetics

State Registration Certificate (SGR)

VEGAN Cosmetics Certification

Vegan certification is certified to cosmetics that do not use animal-derived raw materials, manage the cross-contamination and have not been tested on animals.

Vegan certification requires a strict certification process, which allows consumers to easily choose vegan products without checking the detailed raw materials.

FDA over the counter drug registration (OTC – Over the Counter)

Over-the-Counter cosmetics that can be purchased without doctor's prescription, must be registered with the FDA.

In addition, some cosmetics, such as sunscreen, are classified as cosmetics and OTC at the same time, so all cosmetics and OTC regulations must be complied with.

IGC supports not only OTC registration, but also U.S agent service, which is essential for OTC registration.

EU CPNP (Cosmetic Product Notification Portal)

CPNP is a mandatory system to report products to be distributed in the European market in advance. (EU Cosmetics Regulation No.1223/2009)

The organization can access the entire EU market with just one registration.

IGC supports the entire process including product stability report, preparation for product information file, and RP services.

Halal Cosmetics Certification

Halal is an Arabic word that means "permissible". The Halal certification mark can be given only to products or services produced under Islamic law for use by Muslims.

Companies can export Halal products to Islamic countries after their qualification has been verified that meet requirements of the General Directive on Cosmetics.

IGC provides Halal certification services in cooperation with an international Halal certification body that has both JAKIM (Malaysia) and Eurasian certification schemes

Electrical Electronics Laboratory IAS accreditation No. TL-799

IGC Electrical Electronics Laboratory has obtained ISO/IEC 17025 accreditation from IAS.

IGC LAB test report can be used anywhere in the world IGC LAB has accredited by IAS which concluded MRA with ilac.

Testing field: electrical and electronic products, machinery, medical device, analysis equipment





Food Laboratory IAS accreditation No. TL-832

IGC Food Laboratory has obtained ISO/IEC 17025 accreditation from IAS.

Testing field: food nutrition analysis, Heavy metal test, Food microbial test, Sanitation test









Eurasia Medical Device Registration

Companies that want to export medical devices to Eurasia including Russia must go through Eurasia Medical Device Registration for their products.

In the case of Russia, a medical device registration certificate is issued after evaluation and approval of technical, biological and clinical test results and technical documentation from Roszdravnadzor of the Federal Medical Surveillance Service/Health and Health Ministry.

And after issuance of the registration certificate, it is necessary to additionally obtain individual certification in the respective countries.

CE Medical Device Certification

The legal manufacturer must comply with the requirements of the Medical Device Directive (93/42/EEC) to export medical device to the European market. The legal manufacturers have to be conducted a conformity assessment to attach the CE mark to the medical device, then the legal manufacturer can export their products to European market.

The MDD has been changed to the Medical Device Regulation (EU 2017/745) since May 26, 2021, and the legal manufacturer must meet the requirements of MDR.

If the legal manufacturer obtained the MDD certificate before the compulsory of MDR, it can be used until May 27, 2024.

IGC is working on a medical device certification cooperate with the competent Notified Body (NB). Therefore, the legal manufacturers can apply and proceed the project for most scopes of Class I to Class III. IGC will support that the legal manufacturers obtain the CE certification through a lot of experiences of numerous projects.

FDA Registration of Medical Device

The FD&C Act defines a medical device, and medical devices must comply with FDA regulations and require registration.

Medical devices are classified into Class I, Class II, and Class III according to the degree of risk they may effect to the patient, and most products classified as Class II require a premarket notification, 510(k).

IGC supports the registration of medical devices through the designated FDA Office in California, USA.

European product certification CE

CE LVD/EMC (Low voltage Directive/ Electromagnetic Compatibility)

The Low voltage Directive (LVD) covers protection against electric shock and danger of electrical and electronic equipment within a certain voltage range.

Electromagnetic compatibility (EMC) checks the potential effects by electromagnetic waves from a device and peripheral devices.

LVD Coverage

Rated voltage AC 50~1000 V, DC 75~1,500V

EMC Coverage

Devices that may interfere with electronic devices or may affect product performance by related interference waves

CE MD (Machinery)

CE MD is the European directive to ensure the health and safety of users and operators on various machinery.

The equipment of Machinery Directive such as machineries, safety parts, lifting accessories, chains, ropes and webbing, mechanical transmission device, etc. can be distributed to the European market with CE marking after completing the relevant conformity assessment.

CE PED (Pressure Equipment Directive)

The Pressure Equipment Directive (PED) applies to the design, manufacture and conformity assessment of pressure equipment and assemblies with a maximum allowable pressure of 0.5 bar or higher.

Manufacturers who want to export pressure equipment to the European market can sell them with CE marking after completing the evaluation according to the relevant conformity assessment procedures.

CE PPE (Personal Protective equipment)

CE PPE applies to equipment designed and manufactured to be worn or carried to protect humans from one or more risks related to human health and safety.

Personal protective equipment is classified into three categories according to the risk of the product, and after conformity assessment for each category, the organization can sell to the European market with CE marking.

PPE application items

Mask, protection clothes, protection gloves, respiratory equipment etc.

FDA FFR (Food Facility Registration)

Facilities involving food and animal feed commercially distributed in the United States must be registered with the FDA.

A representative in the United States must be designated at the time of registration of the facility.

FDA facility registrations must be renewed every even-numbered year.

FDA FCE(Food Canning Establishment) & SID(Submission Identifier)

Low-Acid Canned Food (LACF) and Acidified Food (AF) with a moisture activity of 0.85 or higher must be registered with the factory (FCE) and manufacturing process (SID) for each product and issued with a number.

Acidified Food (AF) is a food with a PH 4.6 or less and a moisture activity 0.85

Low-Acid Canned Food (LACF) is a food with a pH 4.6 or higher and a moisture activity 0.85 or higher.

Eurasia EAC certification

EAC certification or State Registration is required for food export to Eurasia including Russia.

General food

EAC DoC (TR CU 021/2011 On safety of food product 11 regulations other than food).

Functional and specialty foods

State Registration Certificate (SGR) - Mineral water, bottled water, soft drinks, special foods including supplements, food additives, etc.

Food



Non-GMO certification

Non-GMO certification is divided into three grades, Grade A (high risk), Grade B (medium risk), and Grade C (low risk) depending on the raw materials and content used.

Products that have obtained Non-GMO certification can provide consumers with an opportunity to choose.

Non-GMO certification is based on the requirements of international standards and regulatory authorities, and does not recognize unintentional mixing.

IGC supports Non-GMO certification through the partner.



Gluten-free certification

Gluten-free certification is applicable to foods that do not contain gluten or are produced by decomposing or removing gluten. Gluten-free certification not only ensures safety as an alternative food for consumers who have been diagnosed with Celiac disease or is allergic to gluten, but also provides a reliable label.

IGC supports Gluten-free certification through the partner.

Vegan certification

Vegan certification is given as a standard for not using animal-derived raw materials, managing to prevent cross-contamination, and not conducting animal testing on products.

IGC supports as an official agent of The Vegan Society in the UK.

Halal food certification

HALAL-certified products mean that they comply with the requirements for not only the raw materials used in the production, but also the workers, production facilities, tools used by employees, work clothes, wrapping paper, label paper, etc.

Halal is an Arabic word that means "permissible". The Halal certification mark can be given only to products or services produced under Islamic law for use by Muslims.

Representative halal includes vegetables, fruits, and fish. Cattle, chickens, ducks, etc. must be livestock products slaughtered according to Sharia law.

IGC works with Halal certification bodies that have JAKIM (Malaysia) and Eurasia certification schemes to provide professional Halal certification services for companies seeking to produce and export Halal products not only domestically but also internationally.

FSMA Accredited Third-Party Certification

IGC was accredited as a third-party FSMA certification body by the US FDA, the first in Korea and the 7th in the world.

IGC has the largest scope of accreditation among the international FSMA accreditation bodies.

FSVP (Foreign Supplier Verification Programs)

FSVP is Foreign Supplier Verification Programs which U.S. importers secure public health when they import food from foreign food suppliers into the United States.

This is a program to verify that food supplied is not contaminated or violates allergen labeling regulations.

IGC supports the FSMA FSVP Certification for FSVP importers by establishing the FSMA Foreign Supplier Verification Program (FSVP) certification process.

VQIP (Voluntary Qualified Importer Program)

VQIP is the Voluntary Qualified Importer Program, a program that allows the FDA to provide customs clearance benefits to food importers so that food can be brought into the United States quickly.

If the importer has participated in VQIP, the supplier must obtain VQIP certification from a third-party certification body such as IGC.



Lead instructor for FSVP



Lead instructor for PCQI

PCQI (Preventive controls Qualified Individual)

According to the FDA FSMA Act, food production facilities must have at least one PCQI expert for FDA FSMA third-party certification.

IGC has been designated the training provider for the PCQI training course and FSVP expert training from the FSPCA (designated as a Lead Instructor), and IGC provides FSMA, PCQI, and FSVP expert training courses for food companies that are exporting or planning to export to the US market.

Auditor Training

IGC has been designated as a training provider for auditor/lead auditor training course by GPC for various management system standards.

IGC Academy provides high-quality training service with expertise and instructors through the abundant audit experience.

IGC provides the accredited personnel certification based on ISO/IEC 17024 with GPC cooperation after completing the auditor training course.

- ISO 9001:2015
- ISO 14001:2015
- ISO 22000:2018
- ISO 22716:2007
- ISO 45001:2018
- ISO 13485:2016
- ISO/IEC 27001:2013
- ISO 21001:2018
- ISO 50001:2018
- ISO/IEC 20000-1:2018
- ISO/IEC 27701:2019
- ISO 37001:2016
- ISO 22301:2019
- ISO 19011:2018
- ISO 15378:2017



Partner **GPC**





IGC provides the personnel certification service through cooperation with GPC, a personnel certification body.

GPC has been accredited the personnel certification in accordance with ISO/IEC 17024 by IAS, an accreditation body in America, and conclude the MLA with IPC.

GPC provides the personnel certification for the following standards.

- ISO 9001
- ISO 13485
 ISO /IEC 20000-1
- ISO 14001
 ISO 22716
- OHSAS 18001 ISO 50001
- ISO 22000
 ISO 45001
- ISO 22301
 ISO 21001
- ISO/IEC 27001 ISO/IEC 27701
- ISO 37001

HONG, GIL DONG
Lead Auditor
ISO 9001:2015

Quality Management Systems

Certification No.
ISSUE date:
Month DD, 20YY
Expiration date:
Month DD, 20YY





Partner RUS-TEST PACIFIC



IGC provides certification services in Eurasia through cooperation with RUS-TEST PACIFIC.

RUS-TEST PACIFIC, as the Korean branch of RUS-TEST, a certification body located in Russia, provides professional services for certification of EAC and GOST in Eurasia including Russia in accordance with various information, knowledge, and technology.

RUS-TEST is an organization that has been accredited by the Russian government as a testing and certification body for EAC and GOST.

The services provided by RUS-TEST PACIFIC for certification in Eurasia are as follows.

- EAC & GOST certification services
- State Registration, Medical Device Registration, PAC (Pattern Approval certificate), Fire Safety Certification, etc.
- Test performing and test report issuance services required for certification
- Eurasia Representative Service
- Russian translation service for the documents required for certification, such as product description, document verification, and technical documents, and Russian interpreting service during the company audit

The major industrial fields in Eurasia

- All industrial fields including food, electronic, machinery, pressure equipment, medical devices, and etc.





