EA EUROPEAN ACCREDITATION

ACCREDITATION
A TOOL TO SUPPORT REGULATORS

What is accreditation?

ACCREDITATION
A service for the Community

Accreditation provides the attestation that accredited bodies offering testing, examination, calibration, certification, inspection and verification services have the technical competence and impartiality to check the conformity of products and services with the relevant national and international standards.

In the European Union, accreditation is performed by national accreditation bodies (NABs) appointed by governments as required by Regulation (EC) 765/2008.

❖ In the regulated area, the law requires accreditation for those bodies that qualify certain categories of products and services (e.g. products with the CE marking such as toys, lifts, food products with protected or guaranteed origin, etc.) which can be put onto the market only after undergoing conformity assessment against the applicable standards. This is notification.

❖ In the voluntary area, where there is no specific legislation, companies seek accreditation to provide the market with an impartial attestation of their competence in guaranteeing products' and services' quality, safety, security, etc.

**IN EUROPE, ACCREDITATION IS GOVERNED
BY REGULATION (EC) 765/2008**

**IN ALL EU MEMBER STATES, GOVERNMENTS
ARE RESPONSIBLE FOR ACCREDITATION**

**ACCREDITATION SUPPORTS BOTH REGULATED
AND VOLUNTARY AREAS**

**ACCREDITATION FACILITATES TRADE AND BENEFITS
THE MARKET AND SOCIETY**

The European system of accreditation

Since 2008, Regulation (EC) 765/2008 establishes the first legal framework for accreditation in Europe, setting out requirements for accreditation relating to the marketing of products.

It gives a harmonized, rigorous approach to accreditation across EU Member States – so that ultimately one accreditation certificate or report will be enough to demonstrate the technical capacity of an accredited body.

The main principles of accreditation in the Regulation – which complements ISO/IEC 17011 and the other international standards for conformity assessment bodies – are:

- ❖ one accreditation body per Member State

- ❖ accreditation is operated as a public authority activity

- ❖ no competition between national accreditation bodies, and between them and conformity assessment bodies

- ❖ not-for-profit activity

- ❖ stakeholder representation

In accordance with article 11 of the Regulation, accreditation provides a presumption of conformity: accredited certificates and reports can be recognised in all EU Member States.

**What is
conformity
assessment?**

CONFORMITY ASSESSMENT
Enhancing confidence in the market

Testing, calibration, examination, inspection, certification and verification services, delivered by accredited bodies (CABs), are collectively known as conformity assessment activities.

Acting as authoritative and impartial entities, national accreditation bodies (NABs) evaluate competence of laboratories, inspection and certification bodies.

NABs guarantee credibility of conformity assessment and reliability of certificates and reports.

Conformity assessment services delivered under accreditation confirm that products and services comply with established requirements – standards and other relevant specifications.

The conformity assessment system is structured in order to give assurance to the public and boost business competitiveness.

In Europe, the conformity assessment system has been improved by the European Commission so as to increase confidence of regulators, businesses and consumers, and to guarantee free movement within the market of goods and services, offering a high level of health protection and safety for consumers and the environment.

All groups of society are involved in ensuring confidence in the products and services put on the market: governments, businesses, clients and end-users.

Better regulation is based on a competent, impartial and effective system where governments, businesses and consumers have a role in maintaining confidence.

REGULATORS

rely on

NATIONAL ACCREDITATION BODIES

which verify the competence of

Laboratories Calibration Testing Medical	**Proficiency Testing Providers**	**Inspection Bodies**	**Certification Bodies** Products Management Systems Persons	**Verification Bodies**

which offer conformity assessment services
to standards/regulatory requirements/scheme criteria

Calibration Testing Examination/ Analysis	**Interlaboratory Comparisons and Proficiency-Testing Programmes**	**Inspection of Products, Processes, Services and Installation or their design**	**Certification of Products, Systems, Persons, Processes or Services**	**Verification of Declarations of Greenhouse Gas Emissions**

for the benefit of

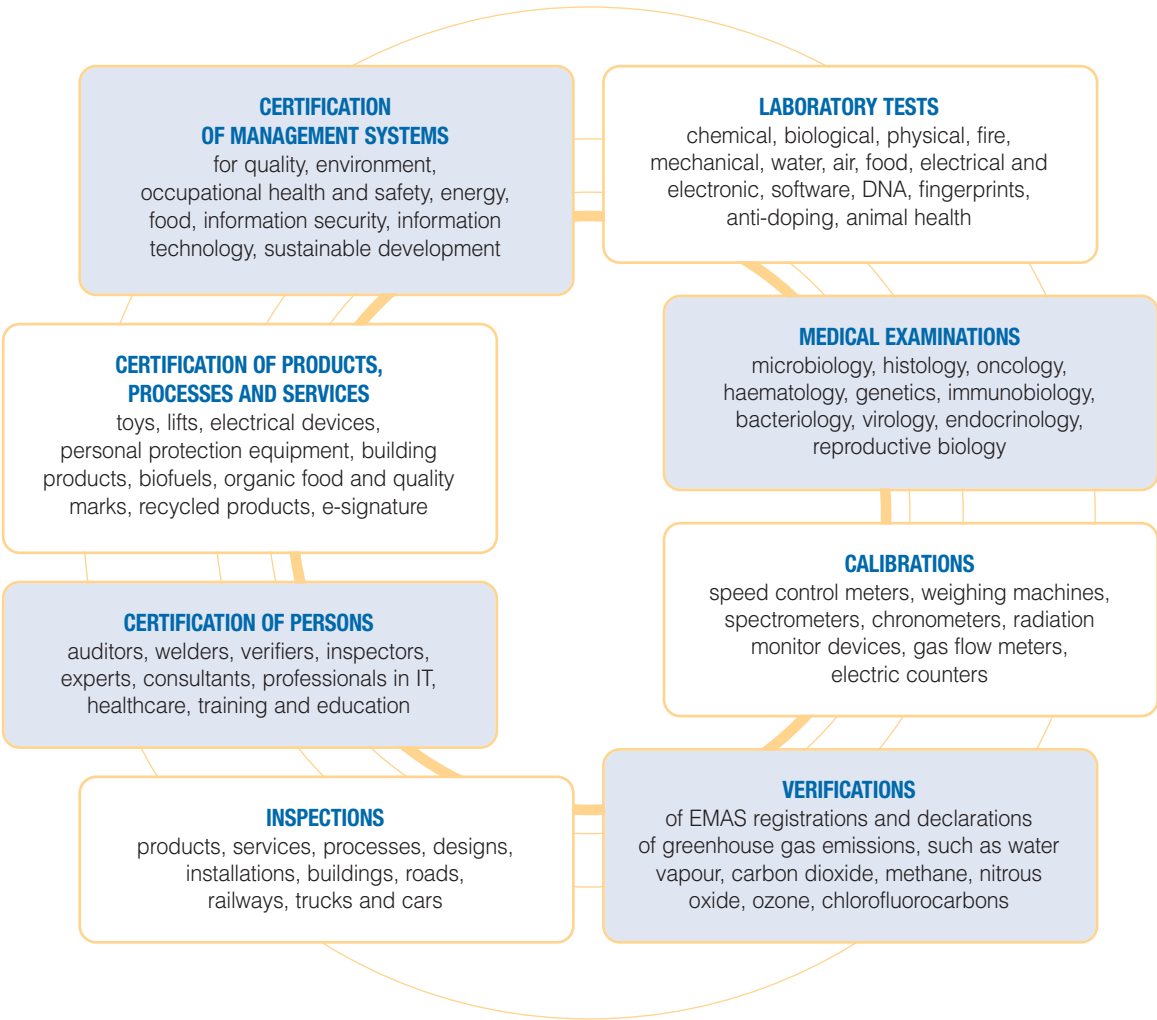| **Governments**	**Businesses**	**Consumers**

on the market of

Products	**Services**

Accreditation is an ongoing process that guarantees the competence of accredited bodies performing conformity assessment services such as:

CERTIFICATION OF MANAGEMENT SYSTEMS
for quality, environment, occupational health and safety, energy, food, information security, information technology, sustainable development

LABORATORY TESTS
chemical, biological, physical, fire, mechanical, water, air, food, electrical and electronic, software, DNA, fingerprints, anti-doping, animal health

CERTIFICATION OF PRODUCTS, PROCESSES AND SERVICES
toys, lifts, electrical devices, personal protection equipment, building products, biofuels, organic food and quality marks, recycled products, e-signature

MEDICAL EXAMINATIONS
microbiology, histology, oncology, haematology, genetics, immunobiology, bacteriology, virology, endocrinology, reproductive biology

CERTIFICATION OF PERSONS
auditors, welders, verifiers, inspectors, experts, consultants, professionals in IT, healthcare, training and education

CALIBRATIONS
speed control meters, weighing machines, spectrometers, chronometers, radiation monitor devices, gas flow meters, electric counters

INSPECTIONS
products, services, processes, designs, installations, buildings, roads, railways, trucks and cars

VERIFICATIONS
of EMAS registrations and declarations of greenhouse gas emissions, such as water vapour, carbon dioxide, methane, nitrous oxide, ozone, chlorofluorocarbons

How is
competence
assured?

ASSURANCE OF COMPETENCE
Providing confidence in reports and certificates results

Accreditation is based on demonstrating compliance with specified requirements for competence, independence and impartiality.

COMPETENCE
The experience and technical skills of the staff in the accredited or applicant body are verified by qualified assessors with relevant expertise and specialised knowledge.
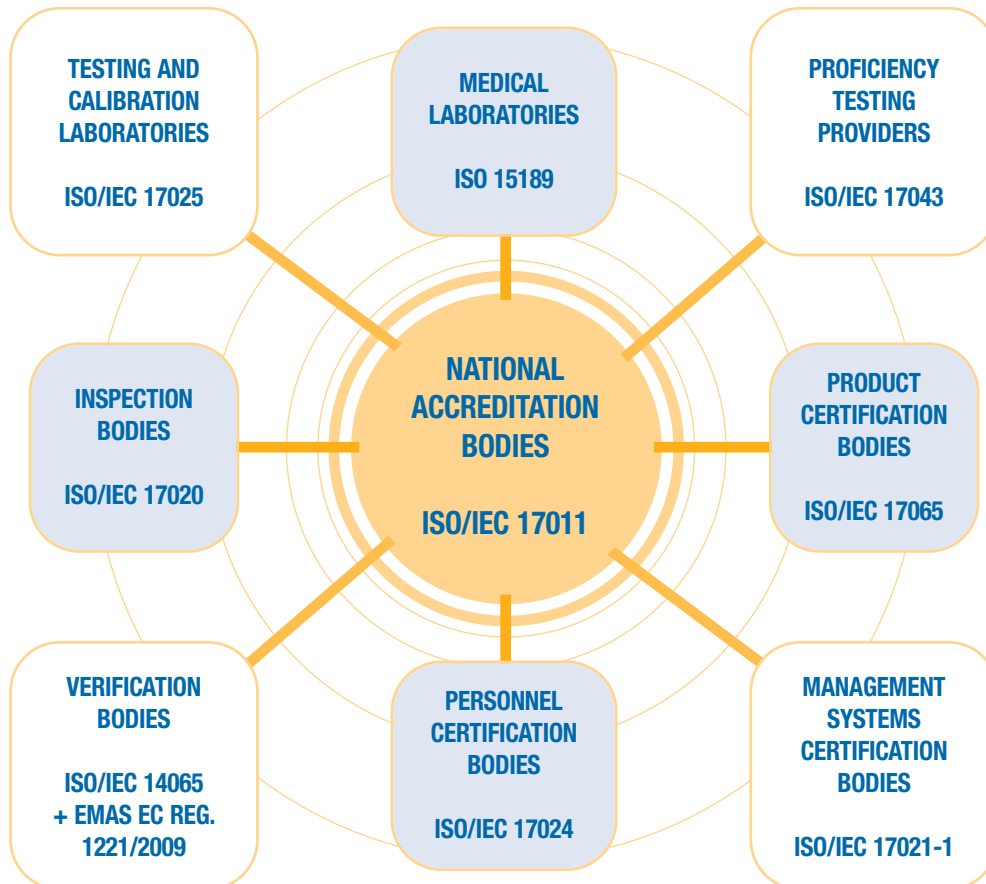
INDEPENDENCE
Accredited bodies that grant certification shall show independence from the organisation to which their services are provided.

IMPARTIALITY
Accredited bodies shall show absence or proper management of conflicts of interest with the client to whom they provide services.

Accreditation

Accreditation is the formal recognition of the technical and organisational competence of a conformity assessment body to carry out specific services in accordance with the standards (ISO, IEC, etc.) or technical regulations as described in its scope of accreditation.

- TESTING AND CALIBRATION LABORATORIES — ISO/IEC 17025
- MEDICAL LABORATORIES — ISO 15189
- PROFICIENCY TESTING PROVIDERS — ISO/IEC 17043
- INSPECTION BODIES — ISO/IEC 17020
- NATIONAL ACCREDITATION BODIES — ISO/IEC 17011
- PRODUCT CERTIFICATION BODIES — ISO/IEC 17065
- VERIFICATION BODIES — ISO/IEC 14065 + EMAS EC REG. 1221/2009
- PERSONNEL CERTIFICATION BODIES — ISO/IEC 17024
- MANAGEMENT SYSTEMS CERTIFICATION BODIES — ISO/IEC 17021-1

The reliability of reports (of test, examination, inspection and verification) and certificates (of calibration and conformity, etc.) is the result of a rigorous and effective process of evaluation of competencies according to international requirements.

Government representatives are welcomed to observe evaluations. The objective is to maintain their confidence in the accreditation system.

INITIAL ASSESSMENT

National accreditation bodies' assessors conduct a thorough evaluation of the applicant's practices, staff and management system, thus verifying compliance with standards. Applicant bodies having successfully passed assessment are accredited. They can use the accreditation mark for the accepted scopes.

ACCREDITATION CYCLE COVERS 2 TO 5 YEARS

National accreditation bodies carry out regular surveillance assessments to ensure that accredited bodies maintain high standards of technical expertise. They can impose sanctions when accredited bodies are not fulfilling all obligations and requirements, and then accreditation scopes can be reduced, suspended or even withdrawn.

EXTENSION OF SCOPES

During the cycle or at renewal, accreditation scopes can be extended to other services, in response to new needs of accredited bodies' customers. Specific assessments are carried out, for instance to be able to perform tests according to a new legislation.

RENEWAL OF ACCREDITATION

At the end of the cycle, accreditation can be renewed after a complete assessment for a new cycle.

EA:
what for?

EA, EUROPEAN CO-OPERATION FOR ACCREDITATION
Supporting the Community and national regulators

National accreditation bodies in EU and EFTA countries are members of EA, the European umbrella of accreditation bodies which ensures the acceptance of accredited certificates and reports on the European and global markets.

EA has been appointed by the European Commission as the "European accreditation infrastructure" to manage accreditation within the EU, EFTA and candidate countries, according to article 14 in Regulation (EC) 765/2008. EA has close relations with the various directorates in the Commission, which it supports in developing regulations. EA is a non-profit association of nationally recognised accreditation bodies, whose main objectives are to:

❖ ensure that national accreditation bodies operate in accordance with the requirements set out in Regulation (EC) 765/2008

❖ harmonise and make accreditation consistent as a public authority activity to support European trade and industry according to its needs and to the requirements laid down in the applicable European legislation

❖ serve as a cooperative network of its members to further a coherent European accreditation system that operates in general European interests

❖ peer evaluate the compliance of national accreditation bodies with the requirements of applicable harmonised standards, European legislation, and other criteria as applicable and agreed by EA

❖ monitor and achieve continuous improvement of its services in all areas of its activities through an effective procedure for the investigation and resolution of complaints and appeals lodged against NABs

What are the international agreements?

INTERNATIONAL AGREEMENTS
The EU and global recognition of reports and certificates

The activities performed by European accreditation bodies are recognised both within the EU and worldwide through their signatory status to the EA Multilateral Agreement (EA MLA).

The EA MLA covers testing and medical examinations, calibration, certification of management systems, products and persons, inspection and verification.

The EA MLA is an agreement signed between EA-member accreditation bodies to recognise and accept the equivalence of their accreditation systems. Thus it provides equal reliability of the certificates and reports issued by the organisations which EA NABs accredit.

This eliminates the need for suppliers of products or services to look for accredited certification / inspection / testing providers in each European country where they sell their products or services.

National accreditation bodies are granted the MLA signatory status only after a stringent **peer evaluation**, of their operations to check their compliance with the internationally agreed standard for accreditation bodies, ISO/IEC 17011, and the specific requirements of Regulation (EC) 765/2008. Peer-evaluations are carried out on a regular basis by experienced staff from other national accreditation bodies. The process is observed by representatives from the European Commission, national authorities and other stakeholders in the business area.

The EA MLA is recognised at the international level by the International Accreditation Forum (IAF) and the International Laboratory Accreditation Cooperation (ILAC). It means that EA MLA signatories benefit from global recognition through the IAF and ILAC mutual agreements and their consequent ILAC/IAF MRA/MLA marks.

What benefits for the public and private sectors?

PUBLIC AND PRIVATE BENEFITS
Advantages for regulators and governments become benefits for consumers and businesses

Developed on the market to facilitate the movement of goods and services where demand for quality and safety is growing, accreditation offers a harmonised, transparent and repeatable approach which:

- ❖ enables innovation

- ❖ reduces the need for governments to employ their own resources

- ❖ builds consumers' and businesses' confidence

- ❖ helps fulfil legal requirements at reasonable costs

For regulators and governments

Testing, examination, verification, inspection, calibration and certification can be used for better control and regulation.

The services provided by accredited bodies, either used directly by regulators and governments or as a tool reference in rules and regulations, demonstrate effectiveness in:

- ❖ supporting implementation of the European or national legislation, providing a "stamp of approval" to confirm compliance with standards and widely accepted requirements

- ❖ qualifying suppliers of goods and services, especially on the procurement market

- ❖ enhancing trade and economic growth, providing governments with reliable data

- ❖ reducing bureaucracy by eliminating a number of administrative obligations

- ❖ limiting costs and resources, by reducing the need for regulators to employ their specialized assessment personnel and by avoiding duplication of audits

- ❖ simplifying the procurement process by ensuring confidence as a decision-making tool

For consumers

Creating trust
Increasingly consumers rely on independent evidence, rather than simply believing in suppliers' advertisements. Consumers' confidence on the market is enhanced when they know that the products and services they choose are regularly evaluated and checked by an independent and competent third party. Choosing a product based on its certification mark, consumers can be sure of the quality of what they are buying.

Protecting, in the public interest
At the other end of the supply chain, consumers' interest is protected by national accreditation bodies acting as "checkers of checkers".

For businesses

Boosting efficiency
Accurate calibration, measurement and testing, performed in accordance with best practice, help limit errors and product failure, improve control of production costs and contribute to an innovative environment. When they obtain certification of their management system, products or services by an accredited body, companies enhance their performance by using a recognised tool for decision-making, risk management and supplier selection. Thus, they enjoy a competitive advantage in terms of reputation and credibility, both on the B2B and consumer markets.

Reducing controls
Accredited certification conveys presumption of conformity with official standards and regulations.
This means that businesses do not need to provide additional evidence, and their activities are simplified subsequent to reduction or elimination of controls.

Supporting export
The international recognition of conformity assessment reports covered by accreditation boosts business expansion on foreign markets without the need to carry out additional verifications.

EFFECTIVENESS IN THE MARKET
Supporting regulators and governments across all sectors

Conformity assessment services spread across a large range of goods and services, which regulators and governments have to maintain public confidence in.

FOOD QUALITY AND SAFETY
control of organic products and quality marks (PGI, PDO, TGS, DOC, DOCG) and laboratory tests of food, including tastings of olive oil and wine

ENERGY SAVING AND ENVIRONMENT PROTECTION
analysis and containment of environmental risks, verification of CO_2 emissions, certification of sustainability, use of biofuels and recycled materials and waste reduction, legionella testing

CONSUMER PRODUCTS
safety inspection and verification, especially of products bearing the CE mark, such as those for children and other potentially dangerous ones (e.g. electrical and electronic equipment, machines, lifts, etc.)

CONSTRUCTION
evaluation of projects and execution of building works, calibration in sound resistance and acoustics, over the functioning of measurement instruments such as electricity and gas meters

HEALTH PROTECTION
medical examinations and certification of medical devices

CRIMINAL INVESTIGATION
forensic analysis, fingerprint examination, DNA database protection, security systems in conformity with sectoral requirements

SAFETY IN THE WORKPLACE
management of procedures aimed at health protection and risk reduction, fire detection and alarm systems

TRANSPORTATION AND INFRASTRUCTURES
control of materials used for highways certification of competence of personnel controlling vehicles and the railway infrastructure, as well as the conformity of payment instruments and highway pay tolls

Visit **www.publicsectorassurance.org** to access case studies and independent research that demonstrate to illustrate how accredited conformity assessment is used around the world by central government, local government and regulators to deliver positive benefit.

THE ADDED VALUE OF ACCREDITATION
Accredited conformity assessment activities

By relying on accredited tests, examinations, verifications, inspections, calibrations and certifications, regulators and governments obtain a third party, independent and competent evaluation, providing objective results to support sound decisions in regulation, public procurement or delivery of products and services onto the market.

Accredited bodies performing such services assure that they meet all required standards, as well as regulatory requirements and sector criteria, in terms of:

- ❖ technical competence, professionalism and integrity
- ❖ risk management
- ❖ adequate human and equipment resources
- ❖ mechanism for measuring improvement of product and service quality
- ❖ complaint and appeal system
- ❖ capacity to compete on an international scale under the EA MLA

When referring to accreditation, it is important to recognise or specify the appropriate requirements for the services or bodies providing them, according to the type of guarantees required.

When selecting an accredited body, it is essential to identify the scope of activities for which the accredited body is granted accreditation; this is detailed on the accreditation certificate.

TEST AND CALIBRATION

Accredited tests and calibrations guarantee accurate and reliable results for a defined set of tests, and ensure that calibrations are carried out in a reliable, competent, consistent and impartial manner and to the correct degree of accuracy.

Accreditation of a testing laboratory means:

❖ validity and appropriateness of test methods
❖ suitability and maintenance of test equipment
❖ proper sampling, handling and transportation of test items
❖ quality control and assurance of test data

Accreditation of a calibration laboratory means:

❖ metrological traceability of calibration results
❖ traceability of operations and recordings
❖ measurements are performed according to validated procedures
❖ reliability of standards and measurement instruments

Accreditation to ISO/IEC 17025 also means that the laboratory meets the management system principles of ISO 9001.

MEDICAL EXAMINATION

Accredited medical examinations assure that clinical laboratories focus on maintaining patients' healthcare, directly connected with improved patient safety, risk mitigation and operational efficiency.

Accreditation to ISO 15189 also means that the laboratory meets the management system principles of ISO 9001.

PROFICIENCY TESTING PROVIDERS (PTP)

Accredited proficiency testing (PT) provides reliable opportunity to undertake comparisons of laboratories' competence and to have an independent appraisal of laboratories' data compared to reference values (or other performance criteria) or to the performance of similar laboratories.

INSPECTION

Accreditation provides assurance of competence of inspectors, relevance of methods for conducting inspections and impartiality of results.

Inspection can be used, in the voluntary and regulated areas, for the assessment of the conformity of a product, project, service, process or installation with relevant requirements based on professional judgement.

MANAGEMENT SYSTEM CERTIFICATION

Management system (MS) certification guarantees that production processes of a product or service are under control and carried out in a systematic way, and that performance is constantly improved and aims to meet clients' requirements.

Accredited MS certifications ensure impartiality in the assessment; auditors are knowledgeable about the activity to be certified and have the relevant expertise.

An organisation is certified only in conformity with the management system standard mentioned on the certificate covering the specified scope, which consists of the certification application field and the detailed processes verified and certified by the competent body. Organisation sites covered by certification are also listed on the management system certificate.

CERTIFICATION OF PRODUCTS, PROCESSES OR SERVICES

A product (i.e. a low energy bulb), a service (i.e. passenger transport) or a process (i.e. organic farming, traceability of timber origins) can be subject to certification.

Product certification aims to the statement by the producer that the product (or process or service) conforms to the relevant requirements. It is not the task of the certification body to declare the conformity of the product, but to attest the trueness of the conformity to the applicable requirements claimed by the producer.

Accredited product certification gives evidence of the independence between the certification body and the manufacturer, and provides presumption of conformity with the applicable legal requirements.

The accredited certificate for the product shall bear the detailed reference to the technical standard or technical specifications which the product is certified in conformity with.

CERTIFICATION OF PERSONS

The accreditation of the bodies certifying persons is either voluntary or compulsory; it may be a statutory requirement for certain professional categories (i.e. non-destructive testing, welding, property, diagnostic surveys, etc.).

The accredited certificate for persons refers to the qualification of the person that the body has evaluated as competent to certify, with the correct reference to the normative document which the person conforms to.

VERIFICATION

According to Regulation (EC) 600/2012, greenhouse gas emissions shall be verified by accredited verifiers, which can operate in more than one EU Member State.

Accredited verification reports can be accepted through all Europe.
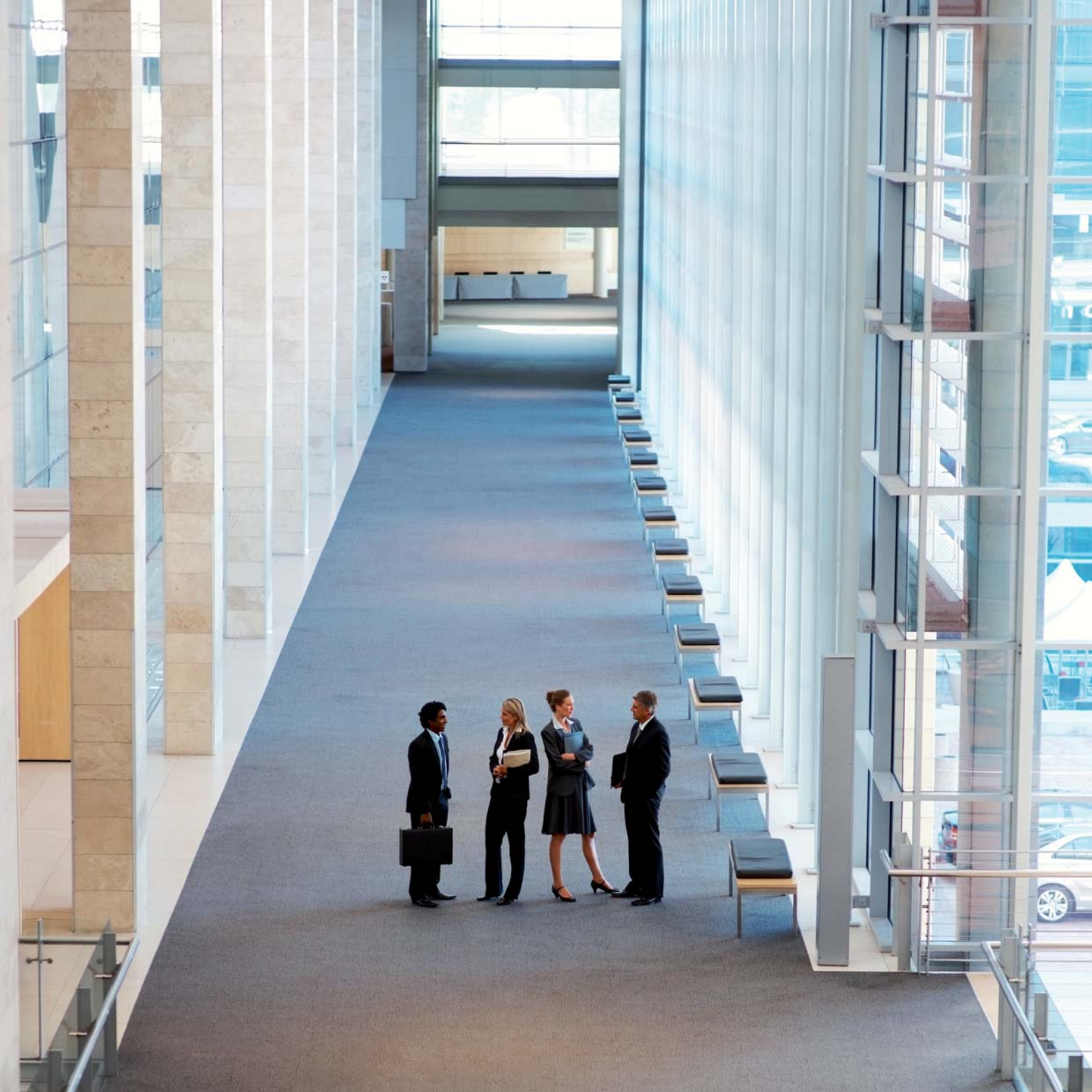
RELIABLE PARTNERS
Accreditation Bodies' Network

Finding out the competent supplier for conformity assessment activities

EA, IAF and ILAC publish the list of accreditation bodies signatories of the EA and IAF MLA (Multilateral Agreements) or ILAC MRA (Mutual Recognition Arrangement), to identify the competent Accreditation Bodies worldwide.

www.european-accreditation.org   www.iaf.nu   www.ilac.org

Moreover, accreditation bodies in most countries publish lists or directories of the bodies and laboratories they have accredited, together with contact details and scopes of accreditation.

EUROPEAN
ACCREDITATION

EA Secretariat
75 avenue Parmentier
F-75544 PARIS Cedex 11
FRANCE
Email: secretariat@european-accreditation.org
Phone: +33 (0)1 40 21 24 62
www.european-accreditation.org

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