



Accreditation
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What is conformity assessment?

Conformity assessment is the process demonstrating whether specified requirements relating to a product, process, service, system, person or body have been fulfilled.

Such requirements can include performance, safety, efficiency, effectiveness, reliability, durability, or environmental impacts such as pollution or noise.

Verification is generally done through testing or/and inspection.

Differences in required conformity assessment procedures constitute major barriers to trade.

**Accreditation acts as a supra layer,
that guarantees impartiality,
confidence in results, and
competence of the assessors.**

**Accreditation rules in Europe are
set up by Regulation (EC)
No 765/2008**





Accredited once, Accepted everywhere

Conformity Assessment is based on international standards, made by International Standardisation Organisations (ISO, IEC, ITU), European Standardisation Organisations (CEN, CENELEC, ETSI), but also by National Standardisation Organisations, Consortia, and local businesses.





Conformity Assessment and accreditation, a key part of national quality infrastructures

The International Network of Quality Infrastructure (INetQI) agreed on a new definition of quality infrastructure systems as “The system comprising the organizations (public and private) together with the policies, relevant legal and regulatory framework, and practices needed to support and enhance the quality, safety, and environmental soundness of goods, services, and processes”



Key players

- International standards organisations, Regulators (European Commission, National Authorities)
- National Accreditation Bodies (as stated in Regulation (EC) No 765/2008, one NAB per country)
- Conformity assessment bodies (CABs) such as laboratories (testing, medical exam, calibration), inspection and certification bodies, Proficiency Testing Providers, etc.
- Interested parties: industry, consumer associations, etc.

Quality Infrastructure and Key Players

MARKET SURVEILLANCE

The **Government Authorities supervise** the market to ensure the free movement of goods that conform with national legislation and with the harmonized European standards for general objectives of health, safety, and environmental protection

STANDARDIZATION

Standardization Bodies define specific voluntary technical requirements with which products, processes, services, systems and persons may comply

REGULATORS

Government and regulators use standards and conformity assessment to set and support policy and regulatory requirements

ACCREDITATION

National Accreditation Bodies attest that a body or laboratory complies with the requirements established in the standards, in terms of competence, independence, and impartiality
> Voluntary and mandatory field

CONFORMITY ASSESSMENT

A **body or laboratory verifies** compliance with the requirements relating to a product, process, service, system or person
> Voluntary and mandatory field

Reg. EC
765/2008



Accredited activities and accreditation standards

MANAGEMENT SYSTEMS CERTIFICATION

ISO/IEC 17021-1

INSPECTION

ISO/IEC 17020

TESTING AND CALIBRATION

ISO/IEC 17025

REFERENCE MATERIAL PRODUCTION

ISO 17034

PERSONS CERTIFICATION

ISO/IEC 17024

VERIFICATION

ISO/IEC 17029

MEDICAL LABORATORIES

ISO 15189

MEDICAL REFERENCE MEASUREMENTS

ISO/IEC 17025
ISO 15195

PRODUCTS AND SERVICES CERTIFICATION

ISO/IEC 17065

VERIFICATION AND VALIDATION

ISO 14065

PROFICIENCY TESTING PROVISION

ISO/IEC 17043


Voluntary and mandatory accreditation

- **VOLUNTARY:** Accreditation is voluntary when requested by bodies that intend to obtain an **independent and authoritative third-party declaration** of their competence and operative correctness
- **MANDATORY:** Accreditation is mandatory for bodies that assess the conformity of specific categories of products, services, processes, systems, and persons, which can be placed on the market only after compliance with the **reference standards required by Laws, Directives or Regulations** has been attested

Benefit for trade



Conformity Assessment and Accreditation save time and money

The image shows a close-up, isometric view of a computer keyboard. The keys are white with black text, except for one prominent blue key in the lower right quadrant that is labeled "TECHNICAL BARRIERS TO TRADE" in white, uppercase letters. The keyboard is set against a dark teal background. The lighting creates soft shadows, giving the keys a three-dimensional appearance. Other visible keys include "P", a key with a tilde and bracket symbol, a key with a double quote and hash symbol, a key with a dash and underscore symbol, a "Ctrl" key, and an "AltGr" key.

A technical barrier to trade (TBT) is any regulation, standard, or procedure that could make exporting goods to another country more difficult. TBTs are often greater obstacles to exporters than tariffs (import fees). Testing or certification procedures are examples of technical barriers to trade.

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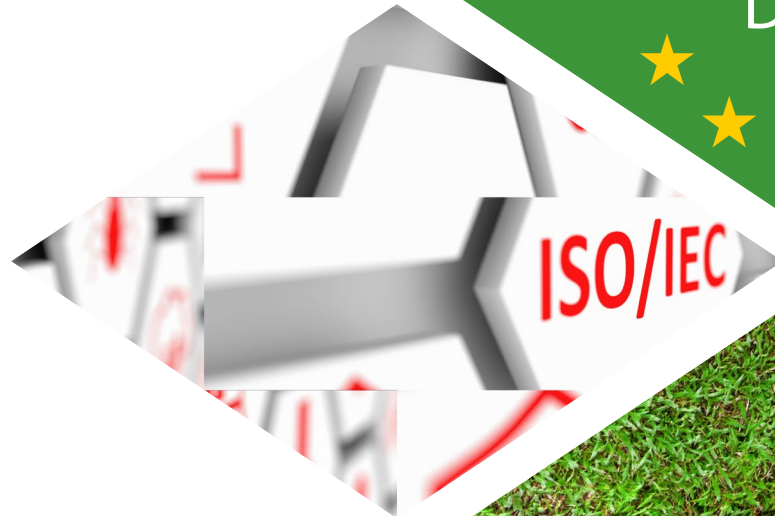
EA is responsible for harmonizing accreditation within Europe, with the aim of reducing barriers to trade and protecting health, safety, and the environment.

For instance, in Europe, without the EA MLA, a product certified in a European country would have to be certified again in each country where the company wished to sell it – a time and money-consuming procedure





International agreements exist signed with ILAC/IAF and agreements between the European Commission and third countries (CETA with Canada)



News in the field of conformity assessment

Digitalization



ASSESSMENT

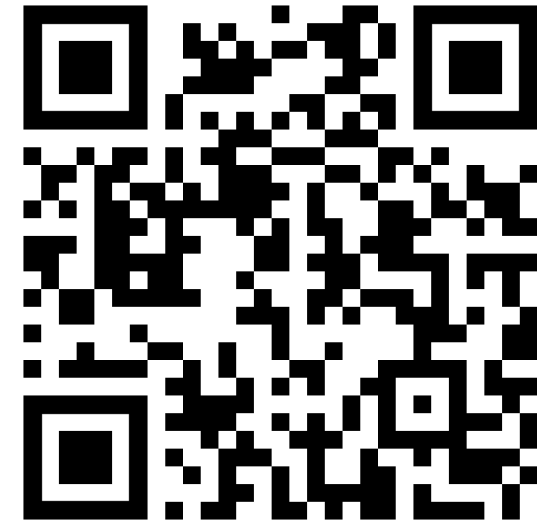
Resources



What is EA? (Short Video)



Accreditation in Europe
Facilitating regulatory
compliance and
international trade



EA's website

Thank you for your attention

