A practical guide for SMEs

What you need to know about **conformity assessment and standards**

Small Business Standards

What is conformity assessment?

Before a product can enter a market, the manufacturer needs to be able to demonstrate that it is safe and performs as promised in terms of safety, reliability, sustainability, energy efficiency and/or other criteria.

Demonstrating **compliance**

Conformity assessment is the name given to the processes used to demonstrate that products, processes, services, persons, systems or bodies meet specific requirements.
Typical examples of conformity assessment activities include testing, inspection, certification or accreditation.

Conformity assessment can be carried out by a first, second or third party:

◇ **First party conformity assessment or self-declaration**
The manufacturer that develops the product declares that it conforms to specific standards or requirements and delivers a declaration of conformity (DoC).

◇ **Second party conformity assessment carried out by the user or purchaser**
A person or organisation who has a direct interest in verifying the performance of a product carries out this conformity assessment. This might be a customer who takes the necessary steps to verify that the characteristics of a product comply with specific technical standards or specifications. For example, a manufacturer may inspect the critical components provided by an outside supplier used in their own finished product.

◇ **Third party conformity assessment carried out by an independent body**
A person or organisation which is independent of the seller or buyer carries out the conformity assessment, usually called certification. This provides the highest level of assurance; however, it is more expensive than first party conformity assessment.
Although conformity assessment and standardisation are separate activities, they are closely related. Conformity assessment depends on the existence of unambiguous specifications or standards against which products, processes, and services can be assessed.

Why is conformity assessment important?

Conformity assessment is important to demonstrate that a product, service or process meets relevant legal, design and safety requirements.

Safety, performance and **reliability**

Conformity assessment plays an important role in ensuring safety, confidence of regulators, businesses and consumers on the products available in the market and supports the free movement of goods and services.

Buyers receive proof through conformity assessment about a product's or system's safety, performance and reliability. Moreover, this gives them access to goods and services of consistent, recognised and reliable quality and safety.

Regulators can verify the compliance with health, safety and environmental requirements and protect the population from unnecessary risks safeguarding the public and building public confidence.

Insurers are provided with the confirmation that risks and relevant safety considerations have been properly managed.

Investors are able to trust that industry-wide best-practice has been applied and their investment is as secure as it can be.

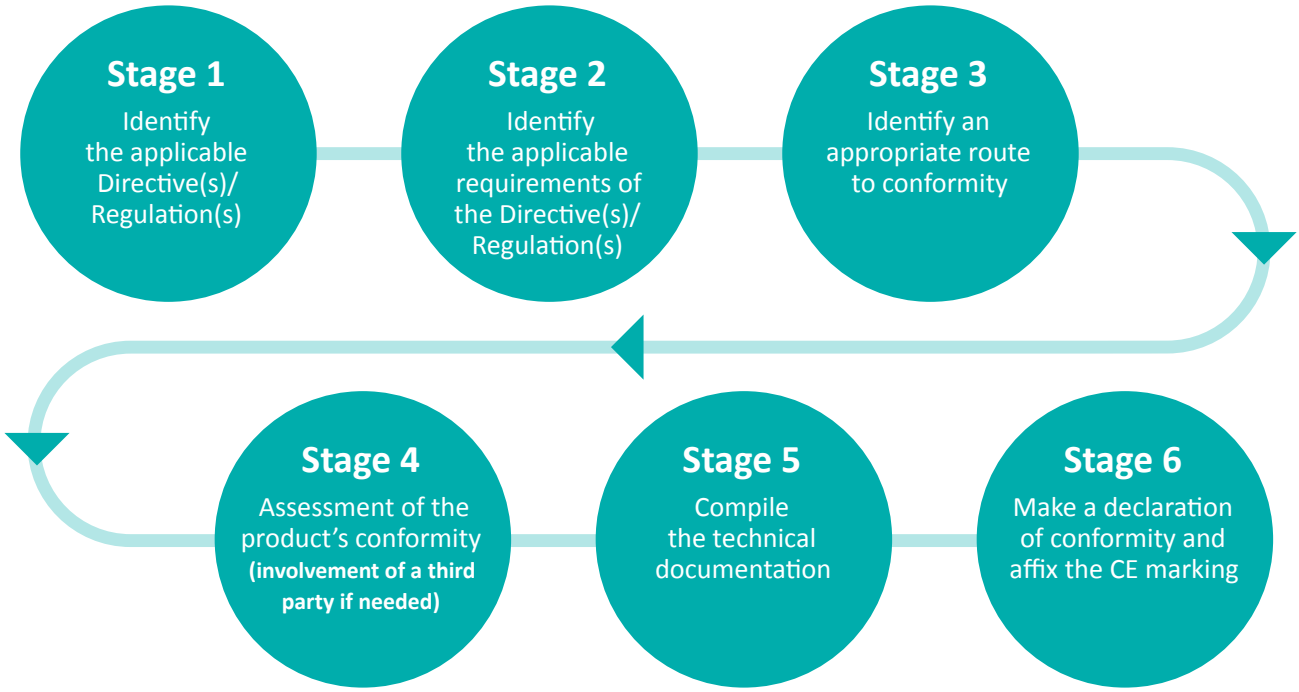
The conformity assessment process used to provide this confidence should be as cost-effective as possible to maximise its value for both the manufacturer/supplier and the buyer.

Conformity assessment and EU legislation

Each EU product regulation or directive includes a number of essential requirements the product must meet before being placed on the market and describes the conformity assessment procedure.

Conformity assessment is a responsibility of the manufacturer. The manufacturer needs to identify the applicable legislation and requirements and may choose between different procedures depending on the EU applicable legislation and classification of the product. Certain products (such as invasive medical devices, pressure equipment, lifts) have a mandatory requirement for the involvement of an authorised third party, a notified body.

Conformity assessment **steps**



Modules for conformity assessment procedures

Eight main modules exist to lay down the responsibilities of the manufacturer and the degree of involvement of an accredited conformity assessment or notified body.

Controls to ensure conformity

The procedures range from A (internal production control) to H (full quality assurance). Some of the modules have some variants (e.g. modules A1 and A2). These modules are described more in detail in Decision 768/2008/EC on a common framework for the marketing of products. It is up to the legislator to choose the module or combination of modules to be used in relation to a specific product and piece of legislation.

Modules	Description
A **Internal production control**	**Covers both design and production.** The manufacturer himself ensures the conformity of the products to the legislative requirements (no EU-type examination).
A1 Internal production control plus supervised product testing	**Covers both design and production.** A+ tests on specific aspects of the product carried out by an in-house accredited body or under the responsibility of a notified body chosen by the manufacturer.
A2 Internal production control plus supervised product checks at random intervals	**Covers both design and production.** A+ product checks at random intervals carried out by a notified body or in-house accredited body.
B **EU-type examination**	**Covers design.** It is always followed by other modules by which the conformity of the products to the approved EU-type is demonstrated. A notified body examines the technical design and or the specimen of a type and verifies and attests that it meets the requirements of the legislative instrument that apply to it by issuing an EU-type examination certificate. There are 3 ways to carry out this type of examination: 1) production type, 2) combination of production type and design type and 3) design type.

Modules	Description
C **Conformity to EU-type based on internal production control**	**Covers production and follows module B.** Manufacturer must internally control its production to ensure product conformity against the EU-type approved under module B.
C1 Conformity to EU-type based on internal production control plus supervised product testing	**Covers production and follows module B.** Manufacturer must internally control its production to ensure product conformity against the EU-type approved under module B. C+ tests on specific aspects of the product carried out by an in-house accredited body or under the responsibility of a notified body chosen by the manufacturer.
C2 Conformity to EU-type based on internal production control plus supervised product checks at random intervals	**Covers production and follows module B.** Manufacturer must internally control its production to ensure product conformity against the EU-type approved under module B.
D **Conformity to EU-type based on quality assurance of the production process**	**Covers production and follows module B.** The manufacturer operates a production (manufacturing part and inspection of final product) quality assurance system to ensure conformity to EU-type. The notified body assesses the quality system.
D1 Quality assurance of the production process	**Covers both design and production.** The manufacturer operates a production (manufacturing part and inspection of final product) quality assurance system to ensure conformity to legislative requirements (no EU-type, used like D without module B). The notified body assesses the production (manufacturing part and inspection of final product) quality system.
E **Conformity to EU-type based on product quality assurance**	**Covers production and follows module B.** The manufacturer operates a product quality (='production' quality without the manufacturing part) assurance system for final product inspection and testing to ensure conformity to EU-type. A notified body assesses the quality system. The idea behind module E is similar to the one under module D: both are based on a quality system and follow module B. Their difference is that the quality system under module E aims to ensure the quality of the final product while the quality system under module D (and D1 too) aims to ensure the quality of the whole production process (that includes the manufacturing part and the test of final product). E is thus similar to module D without the provisions relating to the manufacturing process.
E1 Quality assurance of final product inspection and testing	**Covers both design and production.** The manufacturer operates a product quality (='production' quality without the manufacturing part) assurance system for final product inspection and testing to ensure conformity to the legislative requirements (no module B (EU-type), used like E without module B). The notified body assesses the quality system. The idea behind module E1 is like the one under module D1: both are based on a quality system. Their difference is that the quality system under module E1 aims to ensure the quality of the final product while the quality system under module D1 aims to ensure the quality of the whole production process (that includes the manufacturing part and the test of final product). E1 is thus similar to module D1 without the provisions relating to the manufacturing process.

Modules	Description
F **Conformity to EU-type based on product verification**	**Covers production and follows module B.** The manufacturer ensures compliance of the manufactured products to approved EU-type. The notified body carries out product examinations (testing of every product or statistical checks) to control product conformity to EU-type. Module F is like C2 but the notified body carries out more systematic product checks.
F1 Conformity based on product verification	**Covers both design and production.** The manufacturer ensures compliance of the manufactured products to the legislative requirements. The notified body carries out product examinations (testing of every product or statistical checks) to control product conformity to the legislative requirements (no EU-type, used like F without module B).
G **Conformity based on unit verification**	**Covers both design and production.** The manufacturer ensures compliance of the manufactured products to the legislative requirements. The notified body verifies every individual product to ensure conformity to legislative requirements (no EU-type).
H **Conformity based on full quality assurance**	**Covers both design and production.** The manufacturer operates a full quality assurance system to ensure conformity to legislative requirements (no EU-type). The notified body assesses the quality system.
H1 Conformity based on full quality assurance plus design examination	**Covers both design and production.** The manufacturer operates a full quality assurance system to ensure conformity to legislative requirements (no EU-type). The notified body assesses the quality system and the product design and issues an EU design examination certificate. Module H1 in comparison to module H provides in addition that the notified body carries out a more detailed examination of the product design. The EU-design examination certificate must not be confused with the EU-type examination certificate of module B that attests the conformity of a specimen 'representative of the production envisaged', so that the conformity of the products may be checked against this specimen. Under EU design examination certificate of module H1, there is no such specimen. EU design examination certificate attests that the conformity of the design of the product has been checked and certified by a notified body.

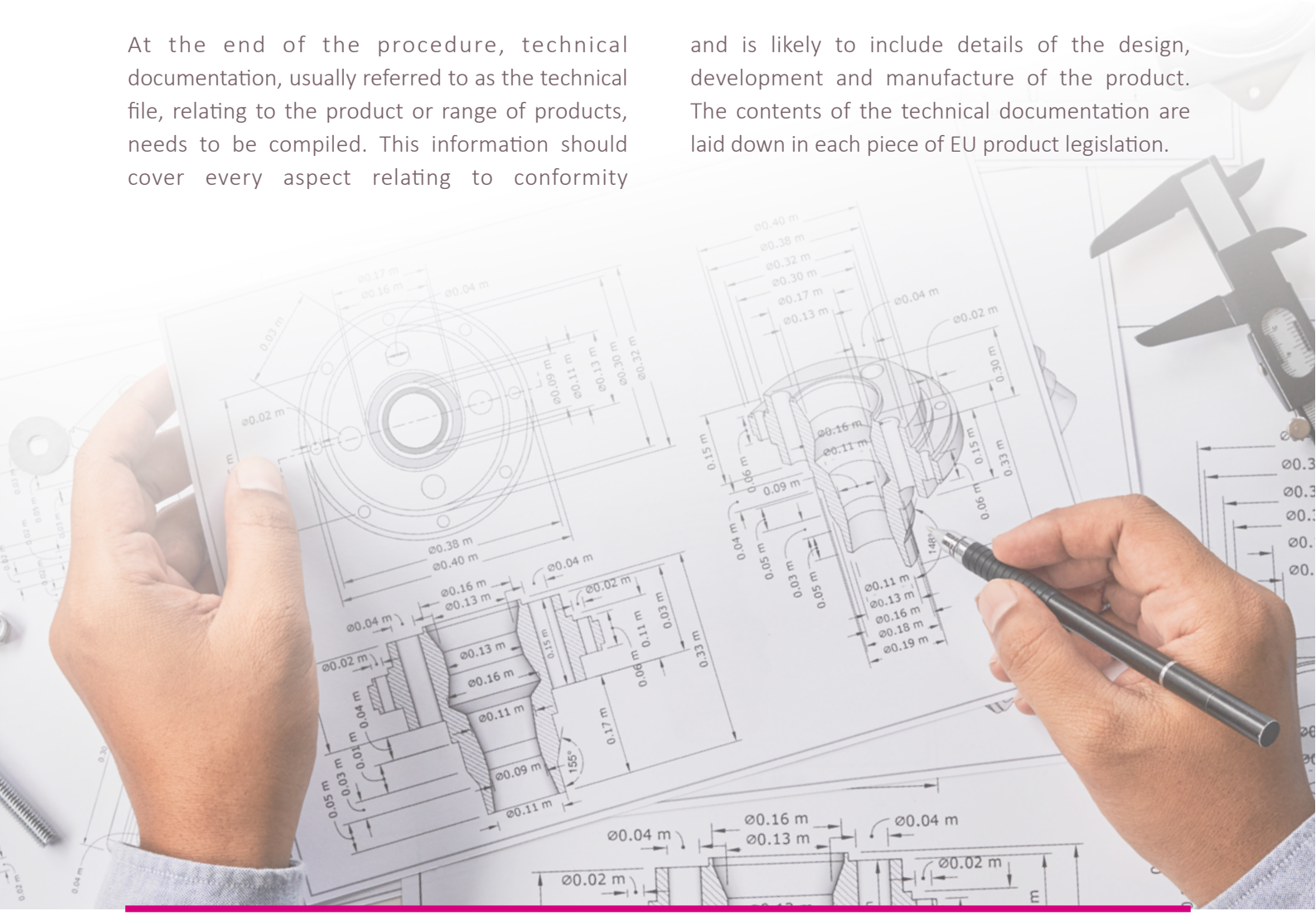
Source: The 'Blue Guide' on the implementation of EU products rules 2016 :
https://ec.europa.eu/docsroom/documents/18027/

Technical file

The technical file includes documentation regarding the design, manufacture and operation of a product. The file must include all the information that is necessary to prove that the product is complying to the applicable requirements.

Compiling **the technical documentation**

At the end of the procedure, technical documentation, usually referred to as the technical file, relating to the product or range of products, needs to be compiled. This information should cover every aspect relating to conformity and is likely to include details of the design, development and manufacture of the product. The contents of the technical documentation are laid down in each piece of EU product legislation.



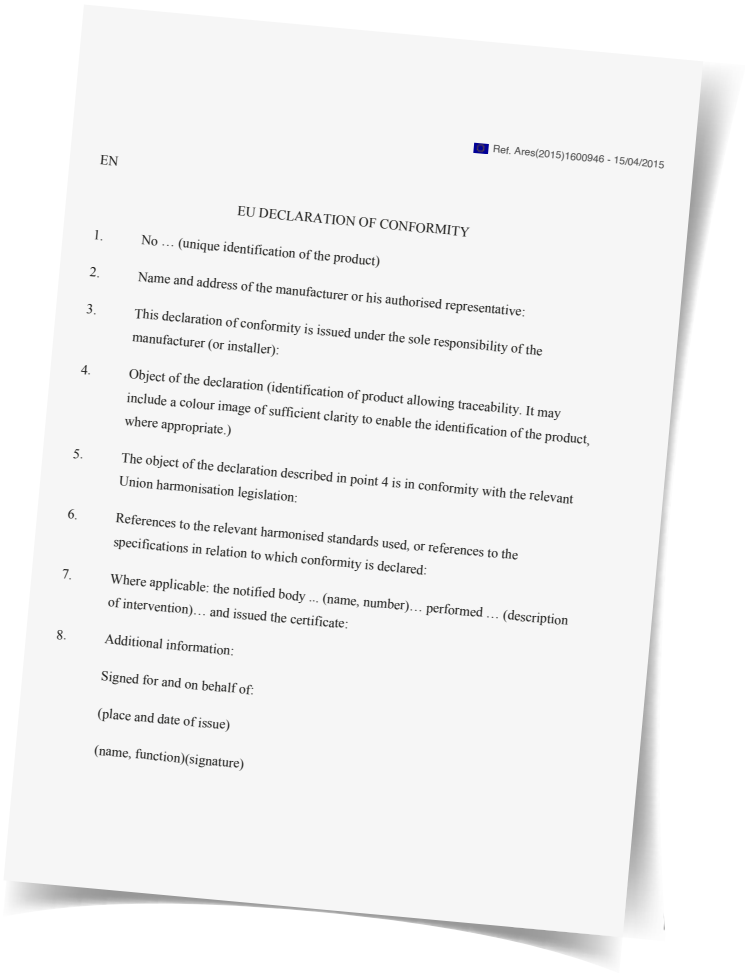
Declaration of conformity (DoC)

As part of the conformity assessment, the manufacturer or the authorised representative must draw up a declaration of conformity.

The EU declaration of conformity is the document that states the product satisfies all the relevant requirements of the applicable legislation. This declaration should contain all information to identify the product, the applicable legislation, the manufacturer or the authorised representative, the notified body if applicable and a reference to harmonised standards or other documents used, where appropriate. By drawing up and signing the EU declaration of conformity, the manufacturer assumes responsibility for product compliance.

The requirements for the declaration vary slightly but will at least include:

- The name and address of the manufacturer or, where appropriate, his authorised representative
- Details and identification of the product (model, description and the serial number where applicable)
- List of applicable legislation and standards and technical specifications that have been applied
- The name and identification number of the notified body involved in the conformity assessment procedure and the reference to the relevant certificate, if applicable
- A statement declaring that the product complies with all the relevant requirements
- Signature, name and position of the responsible person
- The date on which the declaration was signed



EN

Ref. Ares(2015)1600946 - 15/04/2015

EU DECLARATION OF CONFORMITY

1. No … (unique identification of the product)
2. Name and address of the manufacturer or his authorised representative:
3. This declaration of conformity is issued under the sole responsibility of the manufacturer (or installer):
4. Object of the declaration (identification of product allowing traceability. It may include a colour image of sufficient clarity to enable the identification of the product, where appropriate.)
5. The object of the declaration described in point 4 is in conformity with the relevant Union harmonisation legislation:
6. References to the relevant harmonised standards used, or references to the specifications in relation to which conformity is declared:
7. Where applicable: the notified body ... (name, number)… performed … (description of intervention)… and issued the certificate:
8. Additional information:

Signed for and on behalf of:

(place and date of issue)

(name, function)(signature)

CE marking

CE marking indicates that a product meets all the applicable EU legal requirements and it can be legally sold in the European Economic Area (EU Member States, Iceland, Norway and Liechtenstein) and Turkey.

Placing a product **in the market**

The affixing of the mark can only take place after the relevant conformity assessment has been carried out, the technical file has been set up and the DoC has been signed.

It is not a quality indicator, a certification mark nor an indication of the product's origin. The CE marking is mandatory for certain product groups. It is compulsory only when established in the relevant European legislation covering the product. It is forbidden to affix a CE marking to other products. It consists of the CE logo and, in some cases, the four-digit identification number of the notified body involved in the production control phase, if applicable.

Responsibility for CE marking lies with whoever puts the product on the market in the EU, i.e. an EU-based manufacturer, the importer or distributor of a product made outside the EU, or the authorised representative of a non-EU manufacturer.

Notified Bodies

A notified body is an organisation chosen by an EU country to evaluate the conformity of some products before they are placed on the market.

When to involve a notified body

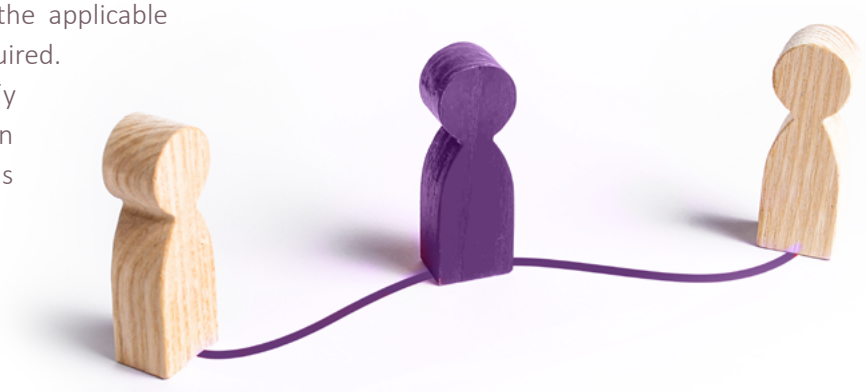
In some cases, the assessment of the compliance of a product with the requirements of EU legislation may require intervention by a third party (notified body) to have the product tested or certified before it is placed on the market. The need to involve a notified body in the conformity assessment procedure depends on the type of product and the specific conformity assessment modules foreseen in relevant EU legislation.

Notified bodies are independent organisations designated by relevant authorities of each EU, EEA Member States and countries with whom the EU has concluded Mutual Recognition Agreements as competent to assess the conformity of certain products before being placed on the market. These bodies carry out tasks related to conformity assessment procedures set out in the applicable legislation, when a third party is required.

The EU Member States notify conformity assessment bodies within their jurisdiction. Notified bodies operate in a non-discriminatory, transparent, neutral, independent and impartial manner and make adequate arrangements to ensure the confidentiality of the information obtained during conformity assessment.

Manufacturers are free to choose any notified body that has been legally designated to carry out the conformity assessment procedure. It is, however, important to take into consideration the technical competence of the body in relation to the specific product and the service needed.

Lists of notified bodies can be found on the NANDO website ("NANDO" stands for "New Approach Notified and Designated Organisations").

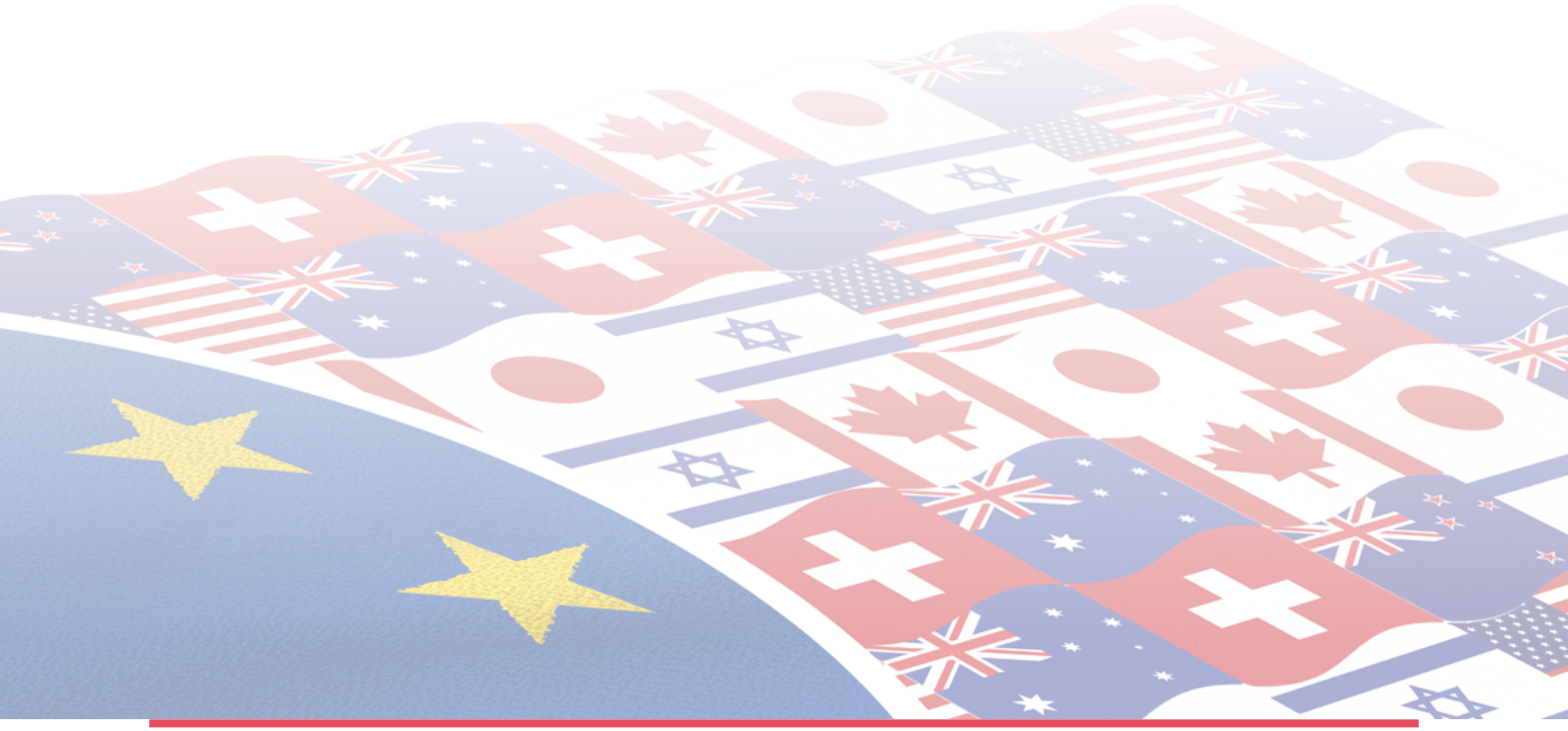


Mutual recognition of conformity by third countries

Numerous Mutual Recognition Agreements (MRAs) exist between the EU and countries such as the US, Japan, Canada, Australia, New Zealand, Israel or Switzerland.

Mutual recognition agreements are bilateral agreements that aim at promoting trade between the European Union and third countries and facilitate market access.

Each agreement lays down the conditions under which the non-EU country will accept conformity assessment results (e.g. testing or certification) performed by the EU designated conformity assessment bodies to show compliance with the requirements in that country and vice versa. MRAs include relevant lists of designated laboratories, inspection bodies and conformity assessment bodies in both the EU and the third country. Further information, including links to existing lists of designated conformity assessment bodies are provided on the European Commission website: https://ec.europa.eu/growth/single-market/goods/international-aspects-single-market/mutual-recognition-agreements_en

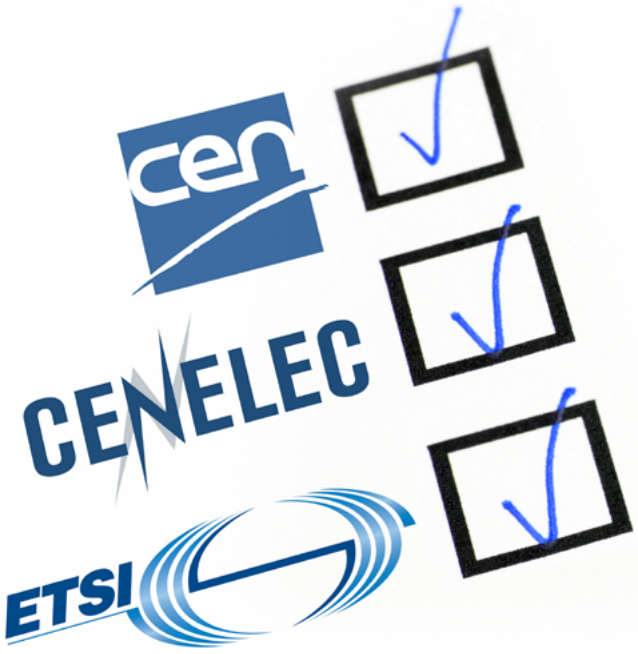


Conformity assessment and standards

Standards, a gateway for SMEs to the single market

Conformity assessment and standards **go hand in hand**

Standards are closely related to any conformity assessment activity. They are often at the basis of conformity assessment procedures by providing clear requirements against which products, services or processes can be assessed. In the case of EU product legislation, the three European Standardisation Organisations (CEN, CENELEC and ETSI) are recognised as organisations that may be requested to produce European harmonised standards in support of sectoral harmonised product legislation. These harmonised standards can be used by manufacturers, conformity assessment bodies and public authorities to assess the conformity of a product with relevant EU legal requirements. The references of harmonised standards are published in the Official Journal of the EU (OJEU). Once referenced, the standards provide a presumption of conformity with the relevant requirements of the legislation covered by the standard.



Conformity assessment and accreditation

Accreditation ensures that conformity assessment bodies carrying out testing, certification and other conformity assessment processes, have the necessary technical competence and impartiality to perform their work.

Accreditation is used in both the regulated and voluntary sectors. It increases trust in conformity assessment. This means that products do not need to be re-tested or re-certified on every new market.

In Europe, Regulation 765/2008 sets the requirements for accreditation. Accreditation is a non-for-profit public sector activity performed by a national accreditation body. Normally, there is one single accreditation body per EU country. The accreditation body checks that a conformity assessment body meets the requirements set by relevant harmonised standards (e.g. ISO/IEC 17000) and, where applicable, any additional requirements including those set out in relevant sectoral schemes, to carry out a specific conformity assessment activity. Accreditation is the preferred means of demonstrating technical capacity of notified bodies in the regulated area.

The role of Small Business Standards

Representing and defending SMEs' interests in the standardisation process

Very often, SMEs are not aware of how important standards are for their trade and daily activities. The main problems are a lack of information on standards, insufficient resources, little knowledge of applicable standards and a need to better understand the standardisation process. It is important that SMEs participate in discussing, writing and updating standards, otherwise their needs may not be taken into account and the final standard may even impose unnecessary or inappropriate requirements on them.

The main goals of SBS are to represent and defend SMEs' interests in the standardisation process at the European and international levels, to raise awareness about standardisation and to motivate SMEs to get involved.

To achieve these objectives, SBS organises training, national seminars and events, and disseminates information on standardisation through various channels. One of its main activities is the appointment of SME experts to relevant standards committees and working groups at the European and international levels.
SBS was established in response to EU Regulation 1025/2012 on European standardisation which aims to make the standardisation system as inclusive, transparent and open as possible. Its activities are funded to a large extent by the European Commission and EFTA.

The association represents the interests of 12 million SMEs through 21 SME member organisations.

Further information on the activities of SBS can be found on its website.

Small Business Standards

Rue Jacques de Lalaing 4
B-1040 Brussels
+32 (0)2 285 07 27
info@sbs-sme.eu
Transparency Register 653009713663-08

@SBS_SME

www.sbs-sme.eu

Co-financed by the European Commission and the EFTA Member States