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Manufacturer's guide for the application of CE Marking in exporting to the European Union

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Abbreviations

CPR	Construction Products Regulation
DoC	Declatation of Conformity
DoP	. Declaration of performance
AVCP	Assessment and Verification of Constancy of Performance
FPC	Factory production control
EAD	European Assessment Document
ETA	European Technical Assessment
NB	Notified Body
TAB	Technical Assessment Body
EOTA	European Organisation for Technical Approvals
ETAG	Guideline for European Technical Approval
hEN	Harmonised European standard
NPD	No performance determined
NANDO	New Approach Notified and Designated Organisations Information System
CEN	European Committee for Standartisation
CENELEC	. European Committee for Electrotechnical Standartisation
EEA	European Economic Area

Introduction

The European Union is based on the idea of an open economy. The growth of trade with EU and non-EU partners has not only increased busines opportunities for small and medium-sized enterprises, but has also brought new risks and challenges in the area of product safety.

Protecting the health and safety of consumers is a priority for the EU. For this reason, product safety is often perceived as a matter of consumer concern only. In fact, European legislation related to product safety is of paramount importance for companies and especially for SMEs. Only safe products can be placed on the market of the European Union

A fundamental prerequisite for selling products on the Community market and benefiting from the free movement of goods is a solid knowledge of compliance with product safety regulations. In case of damage caused by defective goods, the manufacturer is responsible. Consumers tend to buy products from other member countries only if they are sure that the products they use, consume or simply come in contact with are safe.

Accordingly, to truly benefit from the European Single Market and take full advantage of the 490 million consumers within the European Union, companies must ensure that their products are safe. Trading in safe products is also the best way to avoid costly lawsuits and damages.

The European product safety framework covers many pieces of legislation. Laws in different fields provide precise technical rules applicable to a large number of products in different fields, ranging from construction products and electrical equipment to toys, chemicals and cosmetics.

This manual aims to present in a synthesis the new rules for placing on the market products subject to CE marking.

'New Approach' directives are in effect Community laws that must be transposed into the national law of each member state.

This process should allow products legally manufactured or marketed in one country to move freely throughout all member states of the European Union.

By delving into this guide, concepts like the "Declaration of Performance"/ Declaration of conformity and the significance of the "CE" marking will no longer be vague.

For manufacturers, a clearer understanding of obligations and the rationale behind choosing a notified body will emerge. Designers and builders will gain valuable insights to assist in selecting the most appropriate procedure for their needs.

This resource aims to demystify complex regulations, empowering readers with the knowledge required to navigate the intricate landscape of product placement on the market and compliance with CE marking standards.

Key Aspects:

What does the New Approach to Technical Legislation mean?

In order to overcome the obstacles to the free movement of goods, the European Union has developed original and innovative methods, among which the concepts of a New Approach, inwhich the essential requirements forproducts are formulated, and of a Global Approach, in which procedures are foreseen, occupy a privileged place and conformity assessment modules.

What these two complementary approaches have in common is that they reduce the intervention of government authorities to the bare minimum and give producers complete freedom in fulfilling their obligations to consumers.

The "New Approach" is based on the following fundamental principles:

European directives define the **"essential requirements"** to ensure a high level of health and safety protection, consumer protection or environmental protection.

According to the new approach, these directives are adopted on the basis of Article 114 of the Treaty on the Functioning of the European Union (former Article 95 of the EC Treaty), which allows the adoption of measures to improve the free movement of goods;

Products that conform to the European harmonized standards are assumed to meet the relevant essential requirements (presumption of conformity, CE marking) and Member States must accept the free movement of these products;

- Application of these standards is voluntary. It is possible to apply alternative standards, but then manufacturers are obliged to demonstrate that their products meet the essential requirements.

- The new approach requires a refinement of the conformity assessment procedure, in a way that would allow the community legislator to make a proper assessment of the consequences of using different conformity assessment mechanisms.

- The global approach introduces the so-called a modular approach, according to which conformity assessment is divided into a series of operations (so-called modules). These modules differ depending on the phase of product development (e.g. product design, prototype, full production), the type of assessment (e.g. review of available documentation, type approval, quality assurance) and the person who assesses compliance (ie manufacturer or third party)

The global approach was finally confirmed by Council Decision 90/683/EEC, subsequently replaced and updated by Decision No 768/2008/EC of the European Parliament and of the Council of 9 July 2008 on a common framework for the marketing of products, and repealing Council Decision 93/465/EEC (Text with EEA relevance)

From this point onwards, conformity assessment is based on:

- Internal project control and internal production control performed by the manufacturer;

- Type examination performed by a third party combined with internal production control performed by the manufacturer;

- Third-party type or design examination of the product, combined with third-party approval of the product's quality assurance or manufacturing systems, or with third-party product verification

- Verification of the project and of the production of a single product, carried out by a third party

- Third party approval of all quality assurance systems.

It is noteworthy that Council Decision No 768/2008/EC of the European Parliament and of the Council of 9 July 2008 on a common framework for the marketing of products, and repealing Council Decision

93/465/EEC (Text with EEA relevance) not only sets out the guiding principles for the application of conformity assessment procedures in technical harmonization directives, but also harmonizes the rules for placing and using the CE marking.

What are the New Approach directives?

In this guide to New Approach directives, those directives that provide for CE marking are considered. There are also some directives that follow the principles of the New or Global Approach, but which do not provide for CE marking.

Adopted New Approach directives are published in the L series of the Official Journal of the European Communities. Proposals for New Approach directives made by the Commission are published in the C series of the Official Journal of the European Communities.

The provisions in these directives supersede the corresponding national provisions.

- The New Approach Directives are intended for Member States to transpose them into their national legislations in an appropriate manner.

- National laws, regulations or administrative acts which introduce a directive must contain a reference to the directive in question or mention the directive in question when they are officially published.

- Member States must notify the Commission of national laws, regulations or administrative acts adopted and published to implement the relevant directive

Which products are covered by the New Approach directives?

The New Approach Directives applies to products that should be placed on the market (or put into operation) for the first time in the Community. Therefore, the directives apply to new products manufactured in Member States as well as to used and second-hand products imported from third countries.

The concept of "product" varies in different New Approach directives;that is why the manufacturer has the obligation to check whether or not his product falls within the scope of one or more directives.

Products that have undergone significant modifications may be considered as new products and as such must comply with the provisions of the directives that are applicable at the time these products are placed on the Community market or at the time they are placed in action on the territory of the Community.

If there are no provisions to the contrary, product conformity is assessed on a case-by-case basis. Under the New Approach directives, those products which have been subject to a known modification that did not change their technical and operational characteristics, their purpose or their original type, are not subject to conformity assessment.

Products specifically or solely intended for military or police purposes are expressly excluded from the scope of some New Approach directives.

Products covered by directives that provide for CE-marking:

1. Low voltage equipment;
2. Simple Pressure Vessels (SPVD);
3. Children's toys;
4. Construction products;
5. Electromagnetic compatibility;
6. Mechanical;
7. Personal protective equipment;
8. Non-automatic weighting instruments
9. Measuring instruments directive
10. Active medical devices for implantation;
11. Gas appliances;
12. Hot water boilers;
13. Explosives for civil purposes;
14. Medical devices;
15. Equipment intended for operation in a potentially explosive atmosphere;
16. Recreational crafts;
17. (Lifts);
18. Refrigeration appliances;
19. Pressure equipment;
20. Radio equipment;
21. Medical devices for in vitro diagnostics;
22. Radio equipment and terminal telecommunications devices;
23. Unmanned aircraft systems and on third-country operators of unmanned aircraft system

What are the basic requirements?

The basic requirements or the so-called “Essential requirements” define the necessaryelements for the protection of public interests.

- **Essential requirements are mandatory.**

Only products that meet the essential requirements may be placed on the market or put into operation.

The application of the essential requirements depends on the risks inherent in a given product.

One of the main principles of the New Approach is to limit the harmonization of legislation to compliance with essential requirements that are of public importance.

These requirements mainly concern the protection of the health and safety of users (most often consumers and workers) and sometimes cover other fundamental requirements (such as the protection of material assets or the protection of the environment).
The essential requirements are designed to provide and guarantee a high degree of protection.

They arise from certain risks related to the product (e.g. physical or mechanical resistance, flammability, chemical, electrical or biological properties, hygiene, radioactivity, accuracy), concern the product or its technical and operational characteristics (e.g. the regulations regarding the materials used, the design, the construction , the method of production, the documentation prepared by the manufacturer) or establish the main object of protection (for example, through an illustrated list).

How does a manufacturer know which essential requirements apply to a given product?

If your product is covered by a harmonized standard, you should open annex ZA of the standard and check which system of assessment and verification of constancy of performance you should apply for your intended use of the product.

Annex ZA of the harmonized standards is mandatory.

As an example, we have chosen the harmonized standard EN 13241:2003 +A2 "Industrial, commercial, garage doors and gates - Product standard, performance characteristics"

According to Annex ZA, the products covered by the standard are "Industrial, commercial and garage doors and gates according to the scope". There are two tables in Appendix ZA. Table ZA1 sets out the list of essential characteristics to be assessed.

Products: Industrial, commercial and garage doors and gates according to the scope **Intended use(s):** In declared specific uses and/or other uses subject to specific requirements, in particular noise, energy, tightness and safety in use.			
Essential characteristics	**Requirements (clauses in this European Standard)**	**Mandate dlevels and/or classes**	**Test results expressed in**
Watertightness	4.4.1	-	technical classes
Release of dangerous substances	4.2.9	-	See NOTES 1 and 2
Resistance to wind load	4.4.3	-	technical classes
Thermal resistance (where relevant)	4.4.5	-	U-value
Air permeability	4.4.6	-	technical classes
Safe opening (for vertically moving doors)	4.2.8	-	pass / fail classes
Definition of geometry of glass components	4.2.5	-	pass / fail
Mechanical resistance and stability	4.2.3	-	pass / fail
Operating forces (for power operated doors)	4.3.3	-	pass / fail
Durability of watertightness, thermal resistance and air permeability against degradation	4.4.7	-	values

ZA2.2 Gives information about the system against which conformity is to be assessed.

And Table ZA3. Assignation of evaluation of conformity tasks for non fire/smoke doors under system 3

Tasks	Content of the task	
Tasks for the manufacturer	(1) Factory production control (F.P.C.)	Parameters related to all relevant characteristics of Table ZA.1	6.4
	(2) Initial type testing	The following characteristics: • **Geometry of glass** • **Mechanical resistance**	6.2
Tasks for the approved body	(2) Initial type testing	The following characteristics: • **Water tightness** • **Release of dangerous substances** • Resistance to wind load • Thermal resistance • Air permeability • Durability of water tightness, thermal resistance and air permeability • Safe opening • Operating forces	6.2

Do the basic requirements define the technical solution?

The requirements for the products are laid down in the legislation of the European Union. It defines groups of safety requirements in directives. These directives define the essential requirements for the products, and the specific requirements are defined in the so-called harmonized standards.

There are many harmonized standards attached to each directive. The CE marking is an indication that the requirements of each of the applicable Directives have been met.

It is addressed to and protected by the authorities of the Member States .In short: Essential requirements do not obligate us, but if we want to achieve product compliance with regulatory requirements, YES - essential requirements will determine the technical solution.

Does the use of harmonized standards create a presumption of conformity?

Conformity with a national standard which introduces a harmonized standard and whose title and number have been published gives a presumption of conformity with the essential requirements of theapplicable New Approach Directive to which that standard falls.

The titles and identification numbers of the harmonized standards for each specific directive are published in the Official Journal of the European Communities.

An updated list of the titles and numbers of the harmonized standards for each New Approach Directive can be found at the following address:Link:http://europa.eu.int/comm/dg03/directs/dg3b/newapproa/eurstd/harmstds index.html80

Member States must publish the title and number of the national standard that introduces a harmonized standard. It is necessary to clearly indicate the link with the relevant legislation in the publication.

The application of the harmonized standards that give a presumption of conformity is voluntary within the framework of the New Approach directives.
Therefore, a product can be manufactured directly based on the essential requirements.

Why use harmonized standards if their use is not mandatory?

Harmonized standards are documents adopted by European standardization bodies, developed on the basis of a mandate issued by the European Commission. The numbers and titles of these standards are published in the "Official Journal" of the European Union.

When a construction or other type of product is covered by a harmonized standard, the manufacturer must apply the test methods defined in the harmonized standard, which will ensure the use of the common technical language required to complete the declaration of performance.

What is appearing on the market and what is being used?

Where a product is intended to be sold or put into service within the Community, its manufacturer, who is established in a third country, bears the same responsibility for its design and manufacture in accordance with all applicable

New Approach Legislation and for the application of the required procedure for assessing its conformity, as well as the manufacturer, which is established in a given Member State. The manufacturer has the right to designate his authorized representative, established in the territory of the Community, to acton his behalf and at his expense. If the manufacturer is not established in the Community and does not have an authorized representative in the Community, then the responsibilities of the manufacturer or the authorized representative are assumed by the importer or by another person responsible for placing the product on the market

When responsibilities are not taken by any unit responsible for the release of the product, then a product is palced on the market whose conformity has not been assessed.

When does the General Product Safety Directive apply?

The regulation, also known as the General Product Safety Regulation (GPSR), requires companies to ensure that products on sale are safe and to take corrective action when they are found not to be. Implementing Decision (EU) 2019/417 sets out the guidelines for the management of the EU Rapid Information Exchange (RAPEX) system on product safety and the notification system established by Directive 2001/95/EC.

Separate regulations have been introduced for food, pharmaceutical products and medical devices.

This enables national authorities to share information in a timely manner on any measures taken to withdraw such products from sale. This Directive should apply to products regardless of how they are sold, including distance sales and electronic sales.

FULL APPLICATION: The General Product Safety Regulation applies fully to new,used or refurbished non-food consumer products (ie products intended for, or likely to be used by, consumers) not covered by a specific law, such as The "New Approach" directives.

This is the case, for example, with outdoor furniture, gym equipment, baby carriages, baby bottles, paragliding equipment, solid fuels and barbecue lighters, decorative gas lamps, children's bicycle seats and bicycle racks.

Where products are subject to specific safety requirements imposed by Community legislation (eg toys, machinery, low-voltage equipment), the General Product Safety Directive applies mandatorily, e.g. in aspects and risks that are not covered by the specific requirements

Therefore, the General Product Safety Directive does apply partially to consumer products, even if they are covered by the New Approach Directives. As a general rule, the provisions of the General Product Safety Directive Regulation on safety control requirements for manufacturers and distributors,

Member States' market surveillance obligations and the RAPEX system for dangerous products, as well as Community emergency powers, apply to all consumer products, even if they are covered by the New Approach Directive.

Who is liable for damages caused by defective or unsafe products?

Liability for damage caused by defective or dangerous products is borne by every professional in the chain, namely:

a) **Manufacturer** - the manufacturer of the product, when its registered office is in the Community, and any other person presenting himself as a manufacturer by attaching his name, trademark or other distinguishing mark, as well as the person who renews the product;

b) **Authorized** representative of the manufacturer, when the seat of the same is outside the Community, and when there is no representative in the Community - the one who imports the product;

c) **Other** supply chain professionals insofar as their activities may affect product safety;

d) **Employer**, Persons who assemble and persons who install a given product;

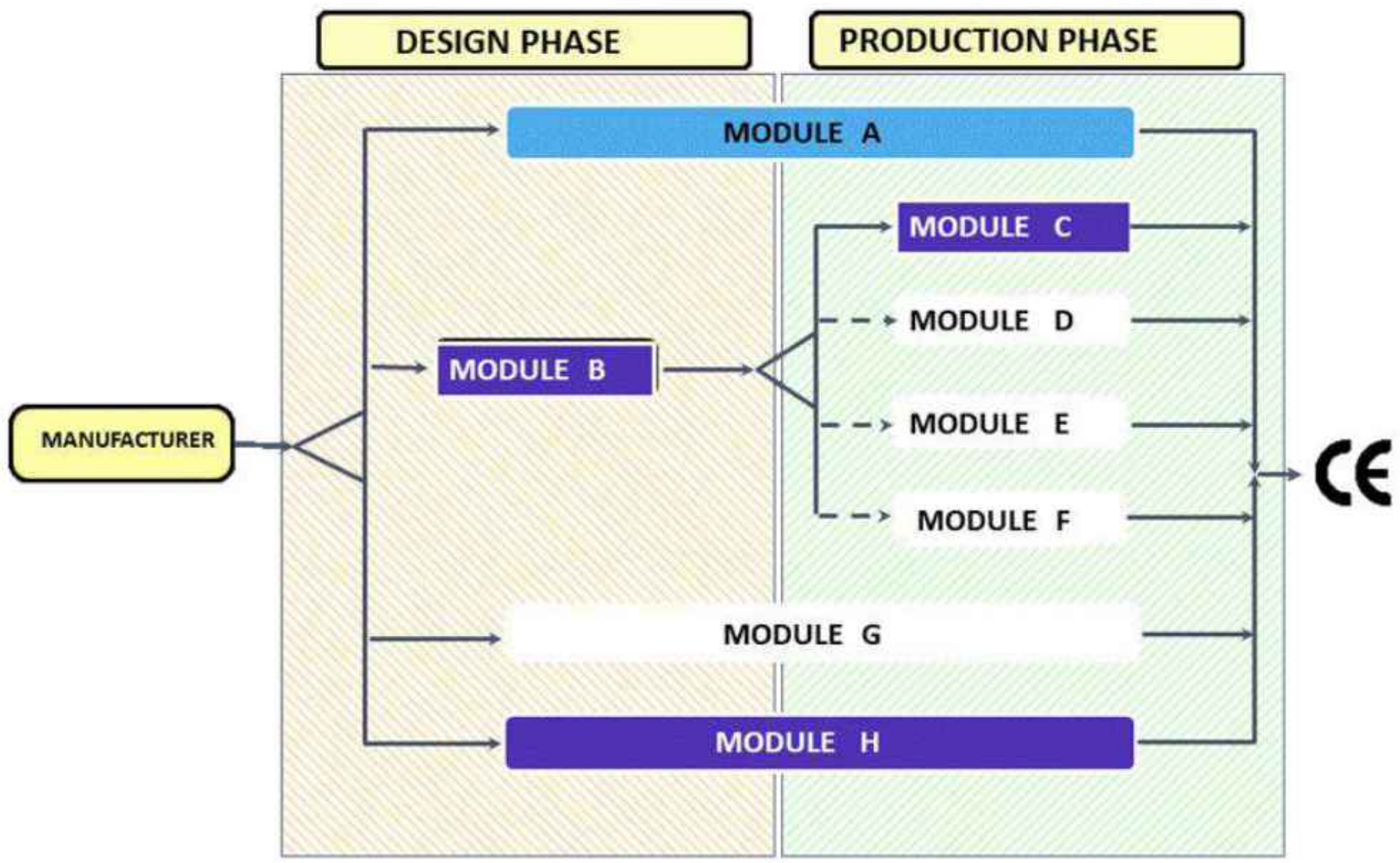
e) "**Distributor**", "importer/person responsible for placing on the market" and any professional in the supply chain whose activity does not affect the safety of the product;

How should compliance be assessed?

Conformity assessment is subdivided into modules that cover different but limited? procedures applied to a wide range of products.Conformity assessment includes modules that cover different but limited procedureslapplied to a wide range of products.

In principle, a product can be subject to conformity assessment according to a given module during the design and production phase

Modules cover the product design phase, the product manufacturing phase, or both. The eight main modules and their eight possible variants can be combined in different ways to establish comprehensive conformity assessment procedures.



Picture 3: Conformity assessment modules of Global Approach

CONFORMITY ASSESSMENT MODULES

Module A - Internal production control

Scope	Covers internal design and manufacturing controls.
Content	It describes the procedure by which the manufacturer fulfills its conformity assessment obligations, ensures and declares that it complies with the requirements of the regulatory act implementing the directive that applies to it. These activities may also apply to the importer or the person who assembles, installs or performs other activities that may affect the conformity of the product.
Manufacturer	1. Compile a technical file, keep it and provide it to the market surveillance authorities upon request 2. Places the mark of conformity on each product 3. Issue a written declaration of compliance and keep at least one copy of it 4. Takes all necessary measures so that the production process guarantees compliance with the product requirements
Notified body	Not participating

Module A1 - Internal production control with final evaluation supervision

Scope	Covers internal design and manufacturing controls. Covers Module A plus additional requirements.
Content	It describes the procedure by which the final evaluation of the product is controlled by spot checks by a notified body chosen by the manufacturer..
Manufacturer	In addition to the obligations provided for in module A, the manufacturer: 1. Performs or has tests performed on each manufactured product 2. Requires random product checks to be performed 3. Chooses a notified body to be responsible for the tests 4. Places the identification number of the notified body after the CE mark when the notified body was involved in the conformity assessment phase during production
Notified body	1. Controls the tests carried out by the manufacturer 2. Monitors the placement of its identification number in case it participates in the conformity assessment during the production phase 3. Takes samples of the finished product and performs or has random product inspections performed 4. Stores the product file 5. Provides (upon request) the necessary information to other notified bodies

Module B- Type Study

Scope	Covers the design phase.
Content	Describes the procedure by which a notified body ascertains and confirms that a sample, which is representative of the production, meets the requirements of the normative act introducing the directive. This module is used with a module that provides the evaluation in the production phase.
Manufacturer	1. Selects a notified body and submits an application for type examination to it, which must contain: - the name and address of the manufacturer - a written declaration that the same application has not been submitted to another notified body - technical documentation required for conformity assessment purposes. 2. Informs the notified body about any changes to the examined product if they affect its compliance with the essential requirements. 3. Stores the technical file, which includes: - the technical documentation - copies of the certificates - additions to them
Notified body	1. Reviews the technical documentation, checks whether the sample was manufactured in accordance with it, determines the components that are designed in accordance with the standards, the components designed without applying standards or designed with partially applied standards 2. Performs or causes to be performed appropriate inspections and/or tests to verify compliance with standards. 3. Performs or commissions appropriate inspections and/or tests to be performed in order to verify, in the event that standards are not applied, whether the adopted decisions comply with the essential requirements. 4. Agrees with the manufacturer the place where the inspections and/or tests will be carried out. 5. Issue to the manufacturer a type examination certificate containing: - the name and address of the manufacturer - the conclusion of the type study - the validity of the certificate - the necessary data for the identification of the researched type. 6. If the issuance of a certificate is refused, give detailed reasons for the refusal 7. Информира другите нотифицирани органи за издадените или отнети сертификати и допълненията към тях.

Module C - Conformity to type

Scope	Covers the production phase.
Content	Describes the procedure by which the manufacturer confirms and declares that the manufactured products conform to the type described in the type examination certificate and comply with the regulations applicable to them. This module follows module B.
Manufacturer	1. Places the mark of conformity on each product 2. Issue a written declaration of compliance 3. Keeps a copy of the declaration of conformity for at least ten years after the production of the last copy of the product 4. Takes all necessary measures to ensure that the manufacturing process ensures conformity of the product with the type described in the type-examination certificate and with the essential requirements.
Notified body	Not participating

Module C1 - Conformity to type with final assessment supervision

Scope	Covers the production phase. Covers module C plus requirements of module C1
Content	Describes the procedure by which the manufacturer ensures and declares in writing that the product conforms to the type described in the type-examination certificate and meets the requirements of the directive applicable to it.
Manufacturer	In addition to the obligations provided for in module C, the manufacturer: 1. performs or commissions tests to be performed on each manufactured product; 2. requires random inspections of the product to be performed 3. selects a notified body to be responsible for the tests 4. place the identification number of the notified body after the CE mark, when the notified body participated in the conformity assessment phase during production

Notified body	1. Controls the tests carried out by the manufacturer 2. Monitors the placement of its identification number in case it participates in the conformity assessment during the production phase 3. Takes samples of the finished product and performs or has random product inspections performed 4. Stores the product file 5. Provides (upon request) the necessary information to other notified bodies

Module C - Conformity to type

Scope	Covers the production phase.
Content	Describes the procedure by which the manufacturer confirms and declares that the manufactured products conform to the type described in the type examination certificate and comply with the regulations applicable to them. This module follows module B.
Manufacturer	1. Places the mark of conformity on each product 2. Issue a written declaration of compliance 3. Keeps a copy of the declaration of conformity for at least ten years after the production of the last copy of the product 4. Takes all necessary measures to ensure that the manufacturing process ensures conformity of the product with the type described in the type-examination certificate and with the essential requirements.
Notified body	Not participating

Module C1 - Conformity to type with final assessment supervision

Scope	Covers the production phase. Covers module C plus requirements of module C1
Content	Describes the procedure by which the manufacturer ensures and declares in writing that the product conforms to the type described in the type-examination certificate and meets the requirements of the directive applicable to it.

Manufacturer	In addition to the obligations provided for in module C, the manufacturer: 1. performs or commissions tests to be performed on each manufactured product; 2. requires random inspections of the product to be performed 3. selects a notified body to be responsible for the tests 4. place the identification number of the notified body after the CE mark, when the notified body participated in the conformity assessment phase during production
Notified body	1. Controls the tests carried out by the manufacturer 2. Monitors the placement of its identification number in case it participates in the conformity assessment during the production phase 3. Takes samples of the finished product and performs or has random product inspections performed 4. Stores the product file 5. Provides (upon request) the necessary information to other notified bodies

Module D - Production quality assurance

Scope	Covers the production phase.
Content	Describes the procedure by which the manufacturer confirms and declares that the manufactured products conform to the type described in the type examination certificate and meet the essential requirements of the regulatory act that applies to them. This module follows module B
Manufacturer	1. Places the mark of conformity on each product. The conformity marking is accompanied by the identification number of the notified body responsible for the supervision of the quality system. 2. Issue a written declaration of compliance. 3. Maintains a certified quality system for production, output control and production testing. 4. Submits a request for assessment of its quality system by a notified body. 5. Stores for a period of at least ten years the documentation of the quality system, decisions and reports from the audits of the notified body.

Module D1 - Production quality assurance without the use of module B

Scope	Covers the production phase. Covers Module D plus the following additional requirements.
Content	It describes the procedure by which the manufacturer maintains an approved quality system for the production, final control and testing of the products and ensures and declares that they comply with the requirements of the directive applicable to them.
Manufacturer	1. Prepares technical documentation containing information on the design, manufacture and operation of the product 2. Implements an approved quality management system covering production, control and testing of the final product 3. Requires evaluation of the quality management system covering the relevant product 4. Ensures and declares that the product complies with the requirements of the directive applicable to it 5. Stores the documentation for the quality management system, as well as data on its modification, decisions and reports from the notified body, in order to provide the supervisory authorities
Notified body	Duties are the same as in module D

Module E - Product Quality Assurance

Scope	Covers the production phase.
Content	Describes the procedure by which the manufacturer confirms and declares that the manufactured products conform to the type described in the type examination certificate and meet the essential requirements of the regulatory act that applies to them. This module follows module B.
Manufacturer	1. Places the mark of conformity on each product. The conformity marking is accompanied by the identification number of the notified body responsible for the supervision of the quality system. 2. Issue a written declaration of compliance. 3. Maintains a certified quality system for output control and production testing. 4. Submits a request for a request for an assessment of its quality system by a notified body. 5. Stores for a period of at least ten years the documentation of the quality system, decisions and reports from the audits of the notified body.

Notified body	1. Evaluates the quality system, ascertains whether it ensures the conformity of the products with the type described in the type examination certificate and with the essential requirements. 2. Conducts periodic audits to ensure that the manufacturer maintains and implements the quality system and submits audit reports. 3. Makes unscheduled visits to the manufacturer and, if necessary, checks whether the quality system is working properly. 4. Informs other notified bodies about the issued or revoked certificates for quality systems.

Module E1 - Product quality assurance without using module B

Scope	Covers the production phase. Covers module D1 plus the following additional requirements.
Content	It describes the procedure by which the manufacturer maintains an approved quality system for the final control and testing of products and ensures and declares that they conform to the applicable requirements of the directive.
Manufacturer	Implements an approved quality management system that covers final product control and testing
Notified body	Duties are the same as in module D

Module F - Product Verification

Scope	Covers the production phase.
Content	Describes the procedure by which the manufacturer checks and confirms that the manufactured products conform to the type described in the type-examination certificate and meet the essential requirements of the regulatory act that apply to them. This module follows module B.
Manufacturer	1. Places the mark of conformity on each product 2. Issue a written declaration of compliance 3. Keep a copy of the declaration of conformity for at least ten years after the production of the last copy of the product 4. Takes all necessary measures to ensure that the production process ensures conformity of the product with the type described in the type examination certificate and with the essential requirements.

Notified body	1. Performs appropriate checks and tests in order to establish the conformity of the product with the requirements of the normative act relating to them 2. Performs control through checks and tests of each individual product and issues a certificate of conformity 3. Carries out control through checks and tests of a sample on a statistical basis from each batch. 4. Takes appropriate measures to prevent non-conforming lot.

Module F1 - Product verification without using module B

Scope	Covers the production phase. Covers module F plus the following additional requirements.
Content	Describes the procedure by which the manufacturer ensures and declares that the product conforms to the type described in the type examination certificate or design examination certificate and to the requirements of the directive applicable to it, i.e. maintains an approved quality system.
Manufacturer	1. Prepares technical documentation containing information on the design, manufacture and operation of the product 2. Takes the necessary measures to ensure that the production method guarantees the compliance of the product with the requirements applicable to it, i.e. implement and maintain an approved quality system 3. In case of statistical verification, present the product in the form of a uniform batch and take measures to ensure that the manufacturing method guarantees the uniformity of each batch produced
Notified body	Duties are the same as in module F

Module G - Single Product Verification

Scope	Covers the design and manufacturing phases.
Content	Describes the procedure by which the manufacturer confirms and declares that the product, for which a certificate of conformity has been issued by a notified body, meets the requirements in the regulatory act that apply to them.

Manufacturer	1. Places the mark of conformity on each product. It is the responsibility of a notified body to place its identification number next to the conformity mark during the manufacturing process 2. Issue a written declaration of compliance 3. Compiles technical documentation for the purposes of conformity assessment, the content of which is determined in the relevant regulatory act.
Notified body	1. Inspects single products and performs or commissions appropriate tests provided for in the standards or testing to verify compliance with essential requirements 2. Issues a written certificate of compliance in connection with the tests performed

Module H - Full Quality Assurance

Scope	Covers the design and manufacturing phases.
Content	Describes the procedure by which the manufacturer fulfills the obligation to maintain a certified quality system for the development, production, final control and testing of the product, guarantees and declares that the manufactured product meets the essential requirements of the regulatory act that applies to it. This module follows module B.
Manufacturer	1. Places the mark of conformity on each product. It is the responsibility of a notified body to place its identification number next to the conformity mark during the manufacturing process 2. Issue a written declaration of compliance. 3. Submits a request for evaluation of a quality system for whether it ensures the conformity of products with the essential requirements 4. Fulfills the obligations relating to the certified quality system and maintains it so that it is adequate and effective 5. Informs the notified body of any planned change in the system 6. Stores for a period of at least ten years the documentation of the quality system, decisions and reports from the supervision of the notified body
Notified body	1. Evaluates the quality system, establishes whether the manufacturer strictly fulfills all obligations arising from the certified quality system 2. Conducts periodic audits to ensure that the manufacturer maintains and implements the quality system and submits audit reports 3. Makes unscheduled visits to the manufacturer and, if necessary, checks whether the quality system is working properly 4. Informs other notified bodies about the issued or revoked certificates for quality systems.

Module H1 - Full quality assurance accompanied by project research and special supervision of final evaluation

Scope	Covers the production phase. Covers Module D plus the following additional requirements.
Content	It describes the procedure by which the manufacturer maintains an approved quality system for the production, final control and testing of the products and ensures and declares that they comply with the requirements of the directive applicable to them.
Manufacturer	1. Prepares technical documentation containing information on the design, manufacture and operation of the product 2. Implements an approved quality management system covering production, control and testing of the final product 3. Requires evaluation of the quality management system covering the relevant product 4. Ensures and declares that the product complies with the requirements of the directive applicable to it 5. Stores the documentation for the quality management system, as well as data on its modification, decisions and reports from the notified body, in order to provide the supervisory authorities
Notified body	In addition to the obligations provided for in module D: 1. Examines the submitted application for project research 2. Issue a project study certificate if it complies with the applicable requirements 3. Maintains a file that contains the project survey certificates and project approvals 4. Informs (upon request) the other notified bodies about the issued or revoked project study certificates and project approvals.

The Construction Products Regulation have a different system of attestation of the conformity assessmet which is the attestation and verification of constancy of performance AVCP provides for five systems for assessing and verifying the performance of the essential characteristics: 1+, 1, 2+, 3 and 4. These systems are described in Annex V of the Regulation and later replaced by the Delegated Regulation (EU) No. 568/2014 of the EC.

Systems for assessment and verification of performance indicators

System 1+

(a) The manufacturer shall carry out:
(i) factory production control;

(ii) further testing of samples taken at the manufacturing plant by the manufacturer in accordance with the prescribed test plan.

(b) The notified product certification body shall decide on the issuing, restriction, suspension or withdrawal of the certificate of constancy of performance of the construction product on the basis of the outcome of the following assessments and verifications carried out by that body:

(i) an assessment of the performance of the construction product carried out on the basis of testing (including sampling), calculation, tabulated values or descriptive documentation of the product;

(ii) initial inspection of the manufacturing plant and of factory production control;

(iii) continuing surveillance, assessment and evaluation of factory production control;

iv) audit – testing of samples taken by the notified product certification body at the manufacturing plant or at the manufacturer's storage facilitie

System 1

(a) The manufacturer shall carry out:

(i) factory production control;

(ii) further testing of samples taken at the manufacturing plant by the manufacturer in accordance with the prescribed test plan.

(b) The notified product certification body shall decide on the issuing, restriction, suspension or withdrawal of the certificate of constancy of performance of the construction product on the basis of the outcome of the following assessments and verifications carried out by that body:

(i) an assessment of the performance of the construction product carried out on the basis of testing (including sampling), calculation, tabulated values or descriptive documentation of the product;

(ii) initial inspection of the manufacturing plant and of factory production control;

(iii) continuing surveillance, assessment and evaluation of factory production control.

System 2+

(a) The manufacturer shall carry out:

(i) an assessment of the performance of the construction product on the basis of testing (including sampling),calculation, tabulated values or descriptive documentation of that product;

(ii) factory production control;

(iii) testing of samples taken at the manufacturing plant by the manufacturer in accordance with the prescribed test plan.

(b) The notified factory production control certification body shall decide on the issuing, restriction, suspension or withdrawal of the certificate of conformity of the factory production control on the basis of the outcome of the following assessments and verifications carried out by that body:

(i) initial inspection of the manufacturing plant and of factory production control;

(ii) continuing surveillance, assessment and evaluation of factory production control.

System 3

(a) The manufacturer shall carry out factory production control.

(b) The notified laboratory shall assess the performance on the basis of testing (based on sampling carried out by the manufacturer),calculation, tabulated values or descriptive documentation of the construction product.

System 4

(a) The manufacturer shall carry out:

(i) an assessment of the performance of the construction product on the basis of testing, calculation, tabulated values or descriptive documentation of that product;

(ii) factory production control;

(b) No tasks require the intervention of notified bodies

All construction products are tested and classified according to EN 13501-1. The testing laboratory issues test reports and classification reports. Based on the test results, we classify construction products into the following fire reaction classes: A1, A2, B, C, D, E and F.

Class A1 designates non-combustible products that do not contribute to the development of uncontrolled combustion, and with class A2 are designated non-combustible products with an extremely limited contribution to the development of uncontrolled combustion.

For construction products of fire reaction classes A2, B, C, D and E, an additional classification is made depending on the intensity of smoke emission (denoted by s1, s2 or s3) and/or the formation of flaming particles or drops at combustion (designated by symbols d0, d1 and d2).

Examples of conformity assessment and issued conformity documents by sectorsc:

Directive 2014/35/EU for electrical equipment intended for use within certain voltage limits

The regulations of the directive, with the aim of harmonizing the legislation of the Member States regarding the design and manufacture of all electrical equipment intended for use with:

- voltage from 50 to 1000 V for alternating current;
- voltage between 75 and 1500 V for direct current.

Conformity assessment procedure:
Module A

A manufacturer of electrical equipment, or his authorized representative established in the Community, guarantees and declares that the electrical equipment complies with the provisions of the directive.

Directive 2000/14 / EC (Directive 2000/14/EC)on the noise emitted by machines and equipment that work outdoors regulatesthe sound power levels of 57 types of machines and equipment specified in the scope of the directive. They are mainly machinery and equipment used on construction sites or in parks and gardens.

For this purpose, the European Commission has developed an electronic EC declaration of conformity form called "Noise", intended for sending and managing documents, which is an online tool for manufacturers, authorized representatives and notified bodies: Noise Emission by Outdoor Equipment

Procedures:

- Internal production control with evaluation of the technical file and periodic inspections of the product
- Single product check
- Approval of a full quality assurance system

For machines/equipment for which the guaranteed sound power level is not limited, but only subject to marking,
the manufacturer must implement a conformity assessment procedure Internal production control, which includes:

- drawing up a technical file;
- all necessary measures for the production process to ensure conformity of the manufactured machine or facility with the technical file and with the requirements of the Directive applicable to it;

- issuance of an EC declaration of conformity;
- placement of the CE mark, subject to compliance with the applicable requirements of the Directive.

REGULATION (EU) 2016/425 of the European Parliament and of the Council of 9 March 2016 on personal protective equipment and repealing Council Directive 89/686/EEC

Regulation (EU) 2016/425 establishes requirements for the design and manufacture of personal protective equipment (PPE) intended to be made available on the market to ensure the protection of the health and safety of users, as well as rules for the free movement of PPE in the European Union .

Personal protective equipment is classified according to the risk categories defined in Annex I of Regulation (EU) 2016/425.

Products that fall within the scope of the Regulation and are classified as category II or category III must undergo mandatory conformity assessment procedures carried out by a third independent party - a notified body.

PPE intended for production must be assessed by such a body and meet the essential health and safety requirements in order to be placed on the market.

We can illustrate each system for evaluating and verifying the constancy of operational indicators with a product for which it is defined:

System 1+: Masonry cement. (EN413-1:2011) Part 1: Composition, requirements and criteria for conformity. The system is applied to the intended use for the production of mortars for brick and block masonry.

System 1: Thermal insulation products for buildings. (EN 13162:2012) Mineral wool products (MW) manufactured in factory conditions. Requirements.

The system is specified for cases where a use is foreseen subject to regulation regarding the reaction to fire of the product, and there is a precise point in the production process of the product at which an additive is used or the amount of organic matter is limited by which is aimed at improving the characteristic "fire reaction" of the thermal insulation product.

System 2+: Bendable waterproofing tarpaulins. Bituminous waterproofing tarpaulins, including bituminous tarpaulins for underground parts of buildings. Definitions and characteristics (EN 13969:2005/ A1:2007) with intended use for limiting the penetration of moisture and vapor.

System 3: Doors and windows. (EN 14351-1:2006+A1:2010) Product standard, technical characteristics. Part 1: Windows and external doors without fire resistance and/or smoke transmission characteristics.

System 4: Decorative wall coverings. Products in the form of rolls and sheets (EN 15102:2007+A1:2011)

What is a notified body?

Notified bodies are responsible for the application of conformity assessment procedures within the meaning of the New Approach directives in cases where the intervention of a third party is required. Member States are responsible for notifying these authorities.

They may notify bodies from among those under their jurisdiction that meet the requirements of the directives and the principles set out in Council Regulation (EC) No.

765/2008 of the European Parliament and of the Council of July 9, 2008 to determine the requirements for accreditation and market surveillance in connection with the marketing of products and to repeal Regulation (EEC) No. 339/93 (Text with EEA relevance) and Decision No 768/2008/EC

of the European Parliament and of the Council of 9 July 2008 on a common framework for the marketing of products, and repealing Council Decision 93/465/ EEC (Text with EEA relevance).

The assessment of the body to be notified determines its competence from a technical point of view, its ability to apply the conformity assessment procedures, as well as the degree of its independence, impartiality and integrity.

In addition, the competence of the notified body is subject to supervision, which is carried out at certain intervals and follows the practice established by the accreditation bodies. Notified bodies assume responsibilities in areas of public interest and are therefore dependent on the competent national authorities.

The difference between the notified body and self-declaration by the manufacturer?

Depending on the functions that the notified bodies perform in the process of evaluating and verifying the constancy of operational indicators, we distinguish three types of notified bodies:

1) product certification bodies participate in the implementation of systems 1 and 1+ for assessment and verification of the constancy of the performance indicators of construction products. They issue a certificate of constancy of performance.

2) production control certification bodies in the enterprise participate in the implementation of the 2+ system for assessment and verification of the constancy of the performance indicators of construction products. They issue a certificate of conformity of production control

3) in the implementation of system 3 for evaluation and verification of the constancy of the operational indicators of construction products, a laboratory participates.

A laboratory can participate at the invitation of the certification body and in the implementation of systems 1 and 1+.

It measures, evaluates, tests or determines, according to the harmonized standard method, the performance indicators of the essential characteristics of construction products.

The notified bodies can be found on the website of the European Commission at the following address: http://ec.europa.eu/enterprise/newapproach/nando/

Products that only need their own declaration?

The conformity of all products not covered by systems 1+, 1, 2+ and 3 is assessed on the basis of non-harmonised standards and other regulatory documents.

In addition, the conformity of all products in construction regulation not covered by systems 1+, 1, 2+ and 3 is assessed on the basis of non-harmonised standards and other regulatory documents.

For these products, the manufacturer issues a declaration of performance/Declaration of the characteristics of a construction product, under his own responsibility (so-called System 4). It is his duty to test the product in: his own laboratory, an accredited laboratory or a control body.

Products that need a Notified Body?

Information on whether your product needs to be assessed by a Notified Body can be found in the relevant legislation that applies to your product: Check the rules by product category at the following address:

Link:
https://single-market-economy.ec.europa.eu/single-market/ce-marking manufacturers_en?prefLang=de

If a notified body is to be involved in the assessment, the "CE" marking must be accompanied by the identification number of that notified body. The "CE" marking and the identification number may be placed separately as long as it is clear that they are interconnected.

The systems for evaluating and verifying the constancy of operational indicators also determine the participation of an independent third party (notified body) in the evaluation process.

Only system 4 does not provide for the participation of a notified body. System 3 requires the tests to be carried out in a notified laboratory, and systems 1+, 1 and 2+ require control by a notified body on production control at the factory.

Schematically, the systems can be represented as follows:

Systems					
	1+	1	2+	3	4
Asks of the producer					
Product type determination based on testing (including sampling) or calculation			X		
Production control	X	X	X	X	X
Additional testing of samples according to a prescribed plan	X	X	X		
Statement of performance	X	X	X	X	X
Tasks of the notified body					
Product type determination based on testing (including sampling for systems 1 and 1+) or calculation	X	X		X	
Initial inspection and assessment of factory production control	X	X	X		
Constant monitoring and evaluation of production control in the enterprise	X	X	X		
Additional testing of samples taken by the enterprise before placing them on the market	X				

Examples of such products are:

Product's name	Decision number of the European Commission and number and title of a standard introducing a harmonized European standard	Conformity Assessment System
1. Special cements	**Decision 97/555/EU** **EN 15743:2010** Supersulfated cement - Composition, specifications and conformity criteria.	**1+**
2. Building lime	**Decision 97/555/EU** **EN 459-1:2010** Building lime - Part 1: Definitions, specifications and conformity criteria	**2+**
3. Construction mortars produced in factory conditions, designed for masonry, supplied as dry mix or ready mortar	**Decision 97/740/EU** **EN 998-2:2010** Specification for mortar for masonry - Part 2: Masonry mortar	**2+**
4. Products and systems / sets for thermal insulation	**Decision 99/91/EU** **EN 14303:2010** Thermal insulation products for building equipment and industrial installations - Factory made mineral wool (MW) products - Specification	1 or 3

List of notifying authorities?

To find a Notified Body that can certify your product, you can use the Nando database.

Link:

https://single-market-economy.ec.europa.eu/single-market/goods/building-blocks/notified-bodies_en

European Commission

Single Market Compliance Space

Home ()> Notified Bodies ()> Search by Legislation

Search by Legislation

Select Legislation name from the list below to find Bodies notified to carry out conformity assessments for this Legislation

Search options

Legislation status

Refine results

Search results (32)

LEGISLATION STATUS Active

Legislation name	Status	PDF list	RSS feed
2000/14/EC Noise emission in the environment by equipment for use outdoors	Active		
2006/42/EC Machinery	Active		
2009/48/EC Safety of toys	Active		
2010/35/EU Transportable pressure equipment	Active		
2013/29/EU Pyrotechnic articles	Active		
2013/53/EU Recreational craft and personal watercraft	Active		
2014/28/EU Explosives for civil uses	Active		
2014/29/EU Simple pressure vessels	Active		
2014/30/EU Electromagnetic compatibility	Active		
2014/31/EU Non-automatic weighing instruments	Active		
2014/32/EU Measuring Instruments Directive	Active		

European Commission

Single Market Compliance Space

Home ()> Notified Bodies ()> Search by country

Search by country

Select Country name from the list below to find Bodies notified to carry out conformity assessments in this Country

Bodies notified under EU legislation (31)

Country	Comment
Austria	
Belgium	
Bulgaria	
Croatia	
Cyprus	
Czech Republic	
Denmark	
Estonia	
Finland	
France	
Germany	
Greece	
Hungary	
Iceland	
Ireland	
Italy	
Latvia	
Liechtenstein	

How to initiate contact with the notifying authorities?

Once you have found the appropriate notifying body for your product, you connect with it and present your products. You ask all the questions that interest you. Notifying authorities do not consult, but can provide guidance for your future joint activity.

The main task of the notified body is to offer services in the field of conformity assessment according to the conditions defined by the directives. It is about services that notified bodies perform for the benefit of producers in the field of public interest.

- Notified bodies can offer their conformity assessment services to any business entity established in or outside the Community. Notified bodies may also carry out these activities on the territory of other Member States or in third countries.

- Manufacturers have the right to choose a notified body from among those that have been designated to apply the conformity assessment procedure according to the applicable directive.

The Commission supports Member States in their efforts to harmonize actions between notifying authorities in relation to the assessment of the competence of bodies to be notified, the application of notification procedures and the exercise of supervision of notified bodies.

- The Commission also monitors, with the help of the Member States, the establishment of close cooperation between notified bodies.

How to read and interpret the results?

The Declaration of Performance (DoP) and declatation of conformity (DoC) stands as a pivotal tool for all stakeholders engaged in the design, implementation, and trade of construction products.

This document plays a critical role in ensuring transparency and facilitating informed decision-making throughout the construction process

In its essence, the DoP must offer a clear definition of the intended use(s) of the product, specifying particular conditions of use.It should encompass acomprehensive list of essential characteristics pertinent to the product's designated use.

This compilation of information provides a reliable overview of the product's performance, enabling effective product comparison in the selection process.

It is noteworthy that construction products may possess additional functional characteristics essential to participants in the construction process. However, if these characteristics do not impact the fulfillment of basic requirements for constructions, they are not deemed essential characteristics under the Construction Products Regulation. As an illustrative example, the color of tiles used for flooring in pedestrian areas, while a crucial selection criterion, does not fall within the regulatory scope as an essential characteristic.

In conjunction with the DoP, manufacturers are required to furnish instructions for use and safety information in the language mandated by the Member State where the product is placed on the market.

This holistic approach ensures that not only the performance aspects but also the safe and appropriate utilization of construction products are adequately communicated to end-users and stakeholders.

The combination of the DoP and accompanying instructions fortifies the regulatory framework, promoting accountability, transparency, and safety within the construction industry.

In this sense, there are two important definitions:

- **"essential characteristics"**: the characteristics of the construction product that influence the basic requirements for construction;
- **"performance "**: the indicators of the essential characteristics defined by level (value), class or description.2

NPD for a performance metric that is not specified

Where the manufacturer does not wish to declare the performance of any essential characteristic, he may enter the NPD when the following two conditions are met: first, he must have already declared the performance of at east one of the specifiedessential characteristics for the intended use of the product, and second - when the characteristic is not required to be declared by the EC or the member state in whose market the product will be provided.

To get a visual idea of the declaration of performance, Annex III of the Regulation gives us a model replaced by the Delegated Regulation (EU) No. 574/2014 of the Commission.

DECLARATION OF PERFORMANCE
№ 01/2023

1. Name and address of the manufacturer, or his authorised representative established in the EEA, and the place of production;

2. Description of the product type and a copy of the information accompanying the CE marking

3. Provisions to which the product conforms:

REGULATION (EU) No 305/2011 of the European parliament and of the council of 9 march 2011 laying down harmonised conditions for the marketing of construction products and repealing Council Directive 89/106/EEC,

4. The number of the accompanying factory production control system certificate;

System 2+
ISO 9001, Certificate Registration №
Test Protocol №

5. This declaration of performance is issued under the responsibility of the manufacturer.Signed for and on behalf of the manufacturer by:

Manager:
Kosovo, 2024 (stamp and signature)

EU DECLARATION OF CONFORMITY

We hereby declare under our sole responsibility that refrigerating unit OME-16T-TFD-500 with serial numbers:

22A300277EM

comply with the basic requirements of following EU Directives:Low Voltage Directive 2014/35/EU Above listed electrical equipment complies with the basic requirements of the Low Voltage Directive 2014/35/EU.

Applied harmonized standards:

EN 60335-1:2012 Household and similar electrical appliances – Safety - Part 1: General requirements.

EN 60335-2-89:2010+A2:2017 Household and similar electrical appliances - Safety - Part 2-89:

Particular requirements for commercial refrigerating appliances with an incorporated or remote refrigerant condensing unit or compressor

Pressure Equipment Directive 2014/68/EU

Above listed product, refrigerating unit is considered as a pressure assembly falling in category III of PED. We hereby declare that product was produced and tested in accordance with requirements prescribed by Module G according to Annex III,
Article 10 of the Directive 2014/68/EU.
The methodology was approved, and testing supervised by TÜV SÜD

Conformity assessment:
Category III – Modul G
(Conformity based on unit verification)

Certificate of Conformity: 13.678.962

Notified Body:

TÜV SÜD Czech s.r.o. Nr. 1017
Novodvorska 994/138,

142 21 Praha 4, Czech Republic

Applied harmonized standards:

EN 378-2: 2016 Refrigerating systems and heat pumps - Safety and environmental requirements - Part 2: Design, construction, testing, marking and documentation

Electromagnetic Compatibility 2014/30/EU

EN 61000-3-3: 2013/A1:2019 Electromagnetic compatibility (EMC) – Part 3-3: Limits – Limitation of voltage changes, voltage fluctuations and flicker in public low-voltage supply systems, for equipment with rated current 16 A per phase and not subject to conditional connection

EN 61000-3-11: 2019 Electromagnetic compatibility (EMC) - Part 3-11: Limits - Limitation of voltage changes, voltage fluctuations and flicker in public low-voltage supply systems - Equipment with rated current ≤ 75 A and subject to conditional connection

EN 61000-3-12: 2011 Electromagnetic compatibility (EMC) - Part 3-12: Limits - Limits for harmonic currents produced by equipment connected to public low-voltage systems with input current > 16 A and < = 75 A per phase

EN 61800-3: 2018 Adjustable speed electrical power drive systems - Part 3: EMC requirements and specific test methods

Ecodesign Directive 2009/125/EC

We declare that the above listed products are compliant with basic requirements of the Directive 2009/125/EC of the European Parliament and of the Council of October 21 st, 2009.

Compliance with this regulation has been verified following the requirements in the Annex V 1a of the EU regulation (EU) 2015/1095 for implementing of the Ecodesign Directive 2009/125/EC.

Product information required in tables 4 and 5 of the regulation are available as per request.

To incorporate this machinery into a refrigerating system the Declaration of Incorporation according to the Machinery Directive has to be observed.

RoHS 2011/65/EU, (EU) 2015/863

We declare that the above listed products and their associated spare parts and accessories are compliant with the requirements of the Directive 2011/65/EU

of the European Parliament and of the Council of June 8th, 2011 on the restriction of the use of certain hazardous substances in electrical and electronic equipment (recast) and the addition of the phthalates asCommission Delegated Directive(EU) 2015/863.

Compliance with this regulation has been verified via internal design controls, supplier declarations and/or analytical test data per the date of this declaration.

DECLARATION OF CONFORMITY

1. Manufacturer -

2. Materials used for the production of ROTATION MOLDED POLYETHYLENE TANKS CONTAINERS

- Polyethylene LLDPE Rotomolding powder RP 384, manufacturer

3. The declaration was created on 10.11.2023;

4. Declares that all manufactured types of tanks/container are in accordance with the requirements of:

- Regulation (EU) No. 10/2011 of the Commission of January 14, 2011 on plastic materials and articles intended for contact with food;

- Commission Regulation (EU) 2018/831 of June 5, 2018 amending Regulation (EU) No. 10/2011 on plastic materials and articles intended to come into contact with food; 3.

- Ordinance No. 2 of 23.01.2008 on the materials and objects made of plastics intended for contact with food;

- Commission Regulation (EU) 2016/1416 of 24 August 2016 amending and correcting Regulation (EU) No. 10/2011 on plastic materials and articles intended to come into contact with food

- Regulation (EU) No. 1169/2011 of October 25, 2011.

None of the food ingredients listed in Annex II - "Substances or products causing allergies or intolerance" are used in the production and are not intentionally put into the manufactured tanks/ containers;

5. In the production of tanks containers, substances that exceed the specific migration limits according to Regulation No. 10/2011/EC – Annex I) are not intentionally added);

6. In production, only granulate (raw material LLDPE Rotomolding powder RP 384) is used, which complies (according to the manufacturers' documents) with the framework of Regulation 1935/2004/EC and Regulation No. 10/2011/EC. Our declaration is also based on test reports for total migration, model solutions A, B and D2:

7. Specifications for the use of the material and/or product: According to the information provided by our raw material suppliers there are no genetically modified organisms

(GMO), palm oil, nano materials and particles, carcinogenic, mutagenic or reproductively toxic substances derivatives of animal substances.

According to the information provided by our raw material suppliers we declare that according to Regulation No. 1907/2006/EU we do not intentionally add phthalates (DEHP, DBP, BBP, DIBP, DIDP, DINP, DMP, DnHP, DnOP, DEP, DMEP), as polymer additives in KPP production.

The declaration does not have validity or a deadline for reissuing, but is valid until changes to: the type of raw material, method of processing, technological equipment, etc., changes to an essential element of the implemented and managed quality system.

Signed for and on behalf of the manufacturer by:

1. Manufacturer - XXXXXXXXXXXXXXXXXXX

Headquarters and production base:XXXXXXXXXXXXXXXXXX

2. Materials used for the production of ROTATION MOLDED POLYETHYLENE TANKS, CONTAINERS with capacity: 200, 500, 1000 liters:

- Polyethylene LLDPE Rotomolding powder RP 384, manufacture: XXXXXXXXXXXXX

3. The declaration was created on XXXXXXXXXX.2023;

4. XXXXXXXXXXXXXX declares that all manufactured types of tanks/ containers are in accordance with the requirements of

- Regulation (EU) No. 10/2011 of the Commission of January 14, 2011 on plastic materials and articles intended for contact with food;

5. In the production of tanks/ containers, substances that exceed the specific migration limits according to Regulation No. 10/2011/EC – Annex I) are not intentionally added);

6. In production, only granulate (raw material LLDPE Rotomolding powder RP 384) is used, which complies (according to the manufacturers' documents) with the framework of Regulation 1935/2004/ EC and Regulation No. 10/2011/EC. Our declaration is also based on test reports for total migration, model solutions A, B and D2:

The declaration does not have validity or a deadline for reissuing, but is valid until changes to: the type of raw material, method of processing, technological equipment, etc., changes to an essential element of the implemented and managed quality system. Signed for and on behalf of the manufacturer by:
XXXXXXXXXXXXXXXXX

What documents should be in the technical documentation?

The manufacturer must prepare a technical file (technical documentation) of the product.

The New Approach directives oblige the manufacturer to draw up technical documentation, which must contain information on the product's compliance with the applicable requirements.

This documentation may be part of the quality system documentation if the directive provides for a conformity assessment procedure based on a quality system.

This obligation comes into effect when the product is placed on the market, regardless of its geographical origin.

Why should I compile product technical documentation?

The manufacturer issues the product performance declaration on the basis of technical documentation that contains all the elements and evidence of the applied system for evaluating and verifying the constancy of performance.

What is a product risk assessment?

Product risk assessments are not mandatory in many countries around the world (with the notable exception of US and EU toy assessments).

Examples: TOYS

Manufacturers can find more information on how to preparation of the instructions and safety information in the following documents:

CEN Guide 11 "Product information important to users",

CEN Guide 14 "Information for the purchase of goods and services intended for users'

CEN/TR 13387 "Articles for the care of young children - Safety guidelines", EN 62079:2001 "Compilation of instructions".

Toys conforming to the harmonized standards or parts thereof, details of which have been published in the Official Journal of the European Union,

shall be deemed to conform to the requirements covered by those standards or parts thereof provided for in Article 10 and in Annex II.

The EC declaration of conformity shall contain at least the elements specified in Annex III to this Directive and in the relevant modules established in Annex II to Decision No 768/2008/EC and shall be updated regularly.

The EC declaration of conformity is drawn up according to the model established in Annex III to this directive. It shall be translated into the language or languages required by the Member State on whose market the toy is placed or made available.

Risk assessment along the entire production chain.

- Food chain risk assessment;

- Assessment of the risk of plastics in contact with food;

- Risk assessment when working with facilities;

- Risk assessment in the production and sale of construction products, etc

Every single production area, every single activity in the given area is subject to risk assessment. This is the presumption of safety along the chain, for people, animals and the environment.

At EU level, there are no permanently established rules on how risk assessments should be carried out. However, there are two principles that should always be kept in mind when considering risk assessment:

Step 1. Identification of hazards and persons at risk

Identifying the sources of danger in the workplace and the persons who may be at risk.

Step 2. Assessment of risks and their ranking by degree of importance

Assessment of existing risks (the seriousness and probability of possible harm) and their prioritization by importance.

Step 3. Making decisions about preventive actions and their implementation

Determining the appropriate measures to eliminate or control the risks and taking action. Introducing preventive and protective measures through a prioritization plan.

Step 4. Control and review

The assessment should be reviewed periodically to ensure its relevance. A record of the results of workplace risk assessments should be kept.

Such a register can be used as a basis for:

- Transmission of the information to the interested parties;
- Assessment of whether the necessary measures have been taken;
- Providing evidence for supervisory authorities;
- Any revision when circumstances change.

It is recommended to archive at least the following details:

- Name and position of the person(s) performing the inspection
- The identified hazards and risks
- Groups of workers exposed to specific risks
- Necessary protective measures
- Details about the implementation of the measures, such as name of responsible person and date
- Details of follow-up monitoring and review measures, including dates and people involved
- Details of the involvement of workers and their representatives in the risk assessment process.

Assessment reports should be drawn up with the consultation and participation of workers and/or their representatives and made available to them for reference.

In all cases, affected parties should be notified of the outcome of any evaluation related to their workplace, and of the actions to be taken as a result of the evaluation.

The OiRA tools provide various reports to document the risk assessment performed and the measures decided upon.

Who must draw up and sign the EC declaration of conformity?

A model of the declaration of performance indicators is given in Annex III of the Construction Products Regulation and subsequently replaced by the Annex of DELEGATED REGULATION (EU) No. 574/2014.

It contains the product type defined by the manufacturer, the applied system for evaluating and verifying the constancy of performance (1+, 1, 2+, 3 or 4), the harmonized standard used for the evaluation (as well as the year of its publication) or the number of the European Technical Assessment issued to assess the essential characteristics of the product. In the case of an applied simplified procedure, the number of the required specific technical documentation shall be entered in the declaration.

The manufacturer must declare the performance of at least one essential characteristic for the declared use. When the manufacturer declares the performance of his product, he must also take into account those essential characteristics which are required

for the intended use of the product in the Member State on whose market he will make it available.

He is required to place the CE mark on his products, as well as prepare the necessary technical documentation and draw up and sign a declaration of conformity. Depending on the applicable directive, assessment and certification shall be carried out:

- from an external service, the so-called notified body, or
- in-house quality control system.

The importer of products of a manufacturer not registered in the EU and without an authorized representative in the EU undertakes to provide, upon request, the technical documentation and a copy of the declaration of conformity.

The distributor is obliged to know the legal regulations and is responsible for marketing the goods in accordance with the requirements.

How long should technical documentation be kept?

The technical documentation must be kept for ten years after the date of the last production of the product, unless the directive provides otherwise.

The validity of on the basis of a European Assessment Document (EAD) is five years after the date of expiry of the validity of the European Assessment Document

What does the CE mark logo mean?

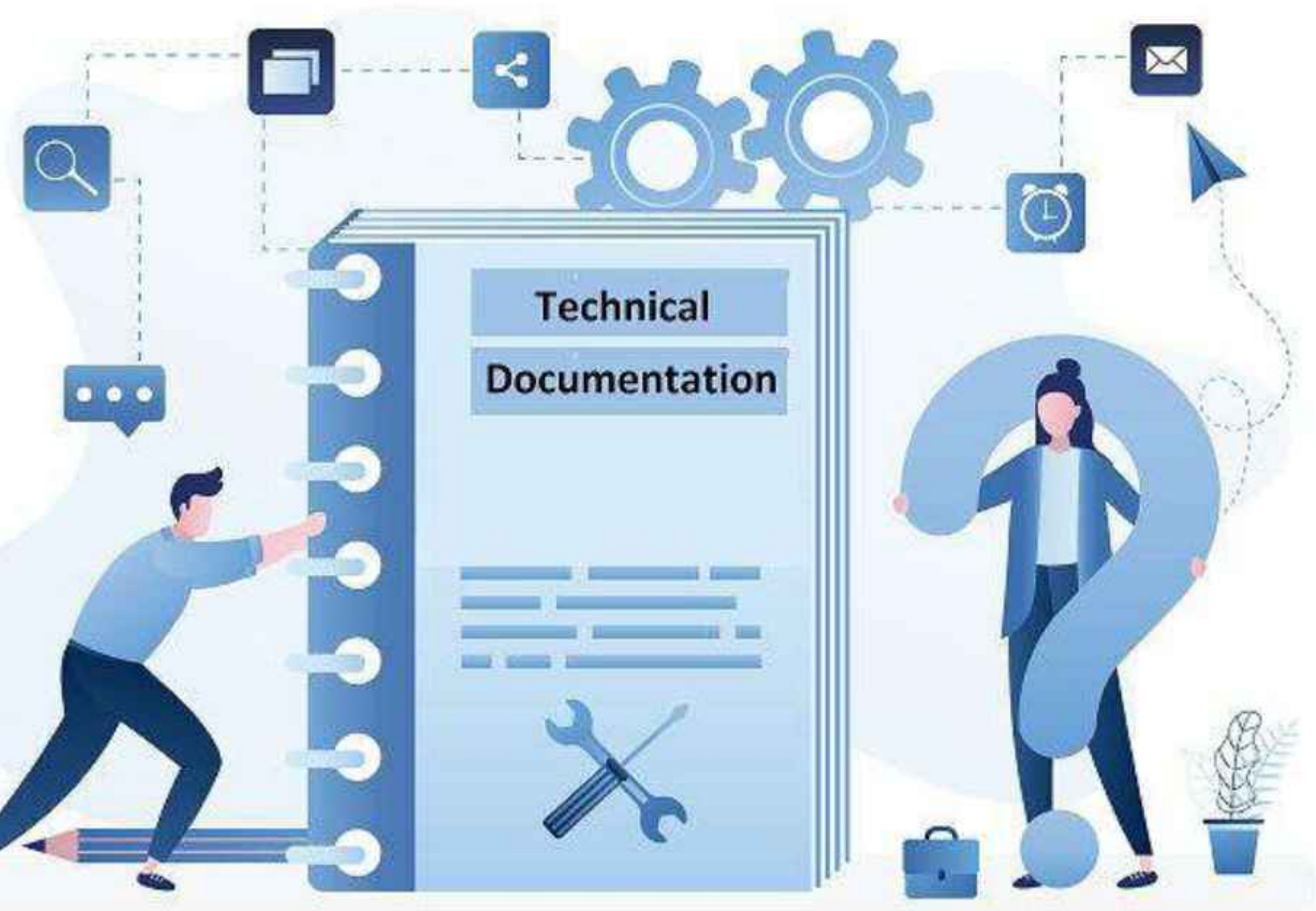
CE is an abbreviation of French (Conformité Européenne) and means "European conformity", and in practice it is a quality management system.

CE marking is required for a number of product categories, such as electrical equipment, pressure vessels, children's toys, construction products,

electromagnetic equipment, machinery. There are also requirements regarding personal protective equipment, medical devices, gas appliances, boilers, vessels, elevators, radio navigation equipment, measuring devices, etc.

The CE marking certifies the conformity of the product with all applicable Community requirements that the manufacturer must comply with.

The CE mark placed on a product is a kind of declaration by the responsible person that the product is in compliance with all applicable Community regulations; all appropriate conformity assessment procedures have been implemented.



CE marking is mandatory and must be affixed before a product is placed on the market or put into service, except where the relevant directives provide otherwise.

• When products bearing the CE mark are covered by several directives providing for its placement, the marking indicates that the products comply with the provisions of the directives in question.

• CE marking may not be affixed to a product unless that product is covered by a directive that provides for its affixing.

The obligation to affix the CE mark applies to all products intended for the Community market that fall within the scope of the directives providing for the affixing of this mark;

• on all new products, regardless of whether they are manufactured in the Member States or in third countries; . The CE marking must therefore be affixed:

• on used and sec ond-hand products imported from a third country;

• on substantially modified products that fall within the scope of the relevant directives as new products.

Some directives may exclude the affixing of the CE marking on certain products, regardless of the fact that the rest of the provisions of the directive are applicable to those products. In principle, such products are subject to the free movement of goods

- if they are accompanied by a declaration of conformity (for example the safety features mentioned in the Machinery Directive and partially completed vessels mentioned in the Recreational Craft Directive);

- if they are accompanied by a declaration of conformity (for example, products that have a minor impact on health and safety, which are listed in the Construction Products Directive);

Are the shape and size described?

The CE marking must be affixed by the manufacturer or by his authorized representative established in the Community.

The CE marking must be in accordance with the form presented below.
In the case of increasing or decreasing the dimensions of the CE marking, its proportions must be respected.

The CE marking must be placed on the product or on its data plate in such a way that it is visible, legible and indelible. When the nature of the product does not allow or justify it, the CE marking is placed on its packaging, if any, and in the documents that accompany the product, when the directives provide for such documents.

• When, within the meaning of the applicable directives, a body is involved in the production control phase, the CE marking must be followed by the identification number of the notified body.

The identification number of the notified body must be affixed by the manufacturer or by his authorized representative established in the Community, the responsibility for its affixing being assumed by the notified body.

For example:

Figure ZA.1 — Example of a label for a manually operated door EN 13241:2003+A2:2016

AnyCo Ltd, PO Box 21, B-1050, Brussels 03 EN 13241 Power operated door Series № or unique № **Water tightness [technical class]** **Resistance to wind load [technical class]** **Thermal resistance [value]** **Air permeability [technical class] CE** (89/106/EC; 98/37/EC; 89/336/EC)	Name or identifying mark and registered address of the producer Last 2 digits of the year in which the marking is affixed Number of the European Standard Description of the product and intended use Identification number Information on regulated characteristics of the product CE conformity marking, consisting of the CE symbol given in Regulation 305

The CE marking is accompanied by the following information:

- the number of the notified body that took part in the evaluation and verification of the constancy of the operational indicators - 5678. We remind you that for system 4, the participation of a third independent party is not required and in this case no number is placed;
- the last two digits of the year in which it was first placed – in our example, these are the digits 13 of 2013.
- the name and address of the manufacturer - they are written even when the manufacturer is not located on the territory of the European Union;
- the number of the declaration of operational performance issued for the product type - 001 CPR 2013-07-14;
- the number of the harmonized technical specification - EN 13249:2002. In case an ETO has been issued for the product, the ETO number will be written here.

- identification code of the product type - "Geotextile geomat 300 non-woven needle punched from polyester staple fibers";

- the intended use of the product for use in road construction and other transport areas;

- the declared performance indicators expressed by level (value), class or description; at the bottom is the address of the electronic page on which the declaration of performance issued for the product is published. The CE marking must be affixed to the product or to its data plate in such a way that it is visible, legible and indelible.

When the nature of the product does not allow or justify it, the CE marking is placed on its packaging, if any, and in the documents that accompany the product, when the directives provide for such documents.

- When, within the meaning of the applicable directives, a body is involved in the production control phase, the CE marking must be followed by the identification number of the notified body. The identification number of the notified body must be affixed by the manufacturer or by his authorized . representative established in the Community, the responsibility for its affixing being assumed by the notified body.

Example of a CE mark

CE Regulation (EU) 305/2011, Chapter VI NB1111
AnyCo Ltd Box 21, B-1050, Brussels DoP Nr. 01/2023
EN 13241 Water tightness [technical class] Resistance to wind load [tech,class] Thermal resistance [value] Air permeability [tech, class]

Practical examples of the procedures for some of the product groups covered by the sectoral legislation and harmonized standards.

Not all construction products are covered by the obligation to be accompanied by a declaration of performance and bear the CE marking.

Before you refuse to use a product because it does not have a CE mark, you should check whether it is required for such a mark.

The following situations actually exist on the market:

1. There is a published harmonized standard for the product and the manufacturer must issue a declaration of performance and affix the CE mark.

During the transitional period of the standard, published in the "Official Journal" of the EU, it is permissible for products of the same group to be legally placed on the market with or without the CE marking and, accordingly, with or without a declaration of performance.

When a new version of an already harmonized standard is published for the product, during the transitional period the products are placed on the market with the CE marking and with a declaration of the performance indicators evaluated according to the old or new version of the harmonized standard.

2. There is no harmonized standard for the product and the manufacturer is not obliged to issue a declaration of performance and affix the CE mark, but one or more manufacturers have requested the issuance of a European technical assessment (ETA) for their/their products.

In this case, products for which an ETO has been issued are accompanied on the market by a declaration of performance and are marked with the "CE" mark. All other products do not carry CE marking and are not accompanied by DEP.

Harmonized standards	The European Assessment Documents
Harmonized standards are documents adopted by European standardization bodies, developed on the basis of a mandate issued by the European Commission. The numbers and titles of these standards are published in the "Official Journal" of the European Union. When a construction product is covered by a harmonized standard, the manufacturer must apply the test methods defined in the harmonized standard, which will ensure the use of the common technical language required to complete the declaration of performance.	The European Assessment Documents are developed and approved by the Organization of Technical Assessment Bodies (EOTA), agreed with the EC, which publishes in the "Official Journal" of the European Union a list of the approved assessment documents. These documents allow a manufacturer to request the issuance of a European Technical Assessment for his specific product for which no harmonized one has been published.

3. There is a harmonized standard for the product and it is accompanied on the market by the DEP and has a "CE" mark, but there are manufacturer/s who take advantage of their right to derogate from this obligation according to Art. 5 of Regulation (EU) No. 305/2011 and do not constitute a DEP, as well as do not put a "CE" mark.

   For them, it is required to draw up the declarations on the characteristics of the construction products or declarations of compliance with the requirements of the investment project for the individual products.

4. No harmonized standard has been published for the product and no European technical assessment has been issued. For all these products, no DEP is drawn up, and no "CE" mark is placed.

EXAMPLE: A manufacturer of doors and windows

1. The product is evaluated based on technical specification (standard) EN 14351-1:2006+A2:2016;

2. We are purchasing Standard EN 14351-1:2006+A2:2016 Windows and doors - Product standard, performance characteristics - Part 1: Windows and external pedestrian doorsets

3. Reference in the Official Journal of the European Union - HARMONIZED;

4. We fulfill the requirements of table ZA. (Table ZA.1 — Relevant clauses (performance characteristics) Construction product: Windows (including roof windows) and external pedestrian doorsets. Intended uses: Communication in domestic and commercial locations.) for conformity assessment/certification of the product.

How does market surveillance and cooperation with customs work?

Market surveillance is an important means of implementing the New Approach directives.

Market surveillance aims to ensure that the provisions of the applicable directives are complied with within the Community. In fact, every citizen of the Community is entitled to the same degree of protection in the territory of the Single Market, regardless of the origin of the product purchased or used.

Market supervision also has a beneficial effect on the interests of economic entities, as it helps to eliminate unfair competition.

Member States must designate or create market surveillance authorities. These bodies must have the necessary resources and have all the necessary rights to carry out market surveillance activities.

Market surveillance includes two main stages:

1) National market surveillance authorities must ensure that the products placed on the market comply with the applicable requirements of the national legislation implementing the New Approach directives;

2) After which, if necessary, the supervisory authorities must take the necessary measures to establish compliance.

Each Member State must notify the Commission and the other Member States when it decides to restrict the free movement of goods due to incorrect affixing of the CE marking or when it takes action against the persons responsible for affixing the CE marking to a non-conforming product

Customs authorities must temporarily prohibit the free movement of products imported from third countries if:

- Consider that certain characteristics of the products may give rise to serious doubts about the existence of a substantial and immediate risk to the health and safety of consumers,
- Ascertain the absence of a document that should accompany the product or the absence of a mark that should be placed on the product according to the requirements related to product safety.

Among the products covered by the New Approach Directives, toys should be subject to special attention by customs authorities during checks for the presence and correct affixing of the CE marking.

Customs authorities are obliged to temporarily prohibit the free movement of goods that possess certain characteristics giving rise to serious doubts about the existence of a substantial and immediate risk that would endanger the health and safety of persons who use these products under normal and foreseeable conditions of us

In this regard, four possible cases must be distinguished:

a) The aforementioned products pose a serious and immediate danger to the health or safety of people;

b) The products do not meet Community or national requirements product safety requirements;

c) The products do not present a serious and immediate risk and cannot be considered non-compliant with the applicable safety requirements;

d) The customs authorities were not informed of any of the measures taken by the market surveillance authorities.

Derogations from the obligation to issue a DEP and CE marking?

Even in cases where a construction product falls under a harmonized standard, if the standard does not include provisions for declaring its performance indicators to both the European Commission (EC) and the member states in which the product is utilized, manufacturers can avail themselves of the provision outlined in Article 5 of the Construction Products Regulation.

This derogation serves as a practical mechanism when the harmonized standard lacks the necessary provisions for declaring performance indicators. In such instances, manufacturers can navigate compliance challenges through the flexibility provided by Article 5.

This provision acknowledges the diverse nature of construction products and ensures that, even when standardization may not cover certain aspects, manufacturers can still adhere to regulatory requirements effectively.

Thus, Article 5 acts as a pragmatic solution, enabling manufacturers to fulfill their obligations in situations where traditional avenues may not be applicable.

1. the construction product is manufactured individually or to the customer's order, not through serial production, but according to a specific request. In addition, this product will be installed on a single well-defined

2. the construction product is produced on the construction site itself to be placed in the relevant construction under the responsibility of those responsible for the safe execution of the construction, according to the applicable national rules; or

3. the construction product is produced in a traditional way or for the purpose of cultural heritage conservation through a non-industrial process for the appropriate renovation of structures protected due to their special architectural or historical value, subject to the applicable national rules.

The derogation allows the manufacturer not to draw up a declaration of performance of his product and not to affix the CE marking.

What are the simplified procedures for assessing construction products?

The Construction Products Regulation has introduced streamlined procedures aimed at alleviating manufacturers of the mandatory testing obligation while still enabling them to prepare a declaration of performance and affix the CE marking.

Within these simplified procedures, manufacturers, in adherence to the specified conditions, have the flexibility to substitute tests or calculations for the operational indicators of their products. In such instances, the manufacturer is required to compile either “appropriate technical documentation” or “specific technical documentation”.

Simplified procedures allow:

- to avoid unnecessary tests (Article 36, a);
- to reduce the number of tests by sharing the results of already performed tests (Article 36, b) and c);
- to facilitate micro-enterprises (Article 37);
- to relieve producers of individually manufactured products

The application of the derogations and simplified procedures requires a very careful familiarization with the above-mentioned articles of the Regulation.

How can I avoid type tests?

The manufacturer may replace the type test or calculation by drawing up appropriate technical documentation in the following cases:

1. **Without testing:** in accordance with the conditions defined in the relevant harmonizedtechnical specification or decision of the Commission, for one or more essential characteristics of the construction product, it is considered that the product achieves a certain level or class of performance indicators without testing or calculation;

Decision 96/603/EC states in Article 1, first paragraph, that:

''The materials and products produced from them, which are listed in the annex to this decision, due to their low flammability and under the conditions also set out in the annex, are classified in classes A1 and class A1FL, as provided for in tables 1 and 2 in the annex to Decision 2000/147/EC.'

2. **Sharing of type test results:** When a product conforms to the type of another construction product produced by another manufacturer and already tested according to the relevant harmonized standard, the manufacturer is allowed to declare performance corresponding to all or part of the results from testing the other product.

This principle applies only to identical products produced in an identical way - from the same input materials and similar production systems. The manufacturer may use the test results obtained by another manufacturer only after receiving written permission to do so from the manufacturer who owns the test reports. This procedure is called ''test result sharing''

An applicable example of sharing test results in our country is the cdetermination of the performance indicators of road safety fences (guardrails), for which the harmonized standard EN 1317-5:2007+A2:2012 ''Restraint systems for roads. Part 5: Product requirements and conformity assessment of restraint systems for road vehicles.'

3. **Cascading of test reports:** The manufacturer of a system of components,which he assembles following the exact instructions of the supplier of the system, who has already tested it with respect to one or more of its essential characteristics, can declare performance indicators corresponding to all or part of the test results of its delivered system.

The system assumes that the assembly of the same components according to the exact instructions of an already assembled and tested system will not result in performance other than that established and no repetition of the tests is necessary.

The scheme is implemented by window manufacturers. Typically, the window profile manufacturer assembles different systems, which it tests in accordance with the harmonized standard, then sells the systems to smaller window manufacturers, along with the right to use the results of the tests it has carried out.

These three simplified procedures are defined by Art. 36 of Regulation (EU) 305/2011, with which you should familiarize yourself very well, in case you want to draw up appropriate technical documentation.In cases where a 1 or 1+ rating system is assigned to the construction product, a notified body for product certification must check the compiled documentation.

SUMMARY

CE marking in 6 steps

STEP 1

Identify the directive(s) and harmonized standards applicable to the product

STEP 2

Validate product specific requirements

STEP 3

Determining the need for an independent conformity assessment by a notified body

STEP 4

Testing the product and verifying its compliance

STEP 5

Prepare and store the necessary technical information

STEP 6

Applying the CE marking to your product and the EC Declaration of Conformity

Step 1

There are more than 20 directives defining the categories of products requiring CE marking. The main requirements that the product must meet (e.g. safety) are harmonized at EU level and are specified in the general conditions of these directives. Harmonized European standards are issued in relation to the applicable directives and reflect the detailed technicalspecifications that meet the essential requirements.

Step 2

It is up to you to ensure that your product meets the essential requirements of the relevant EU legislation. Full compliance of a product with harmonized standards implies that the product conforms to the relevant essential requirements.
The use of harmonized standards remains voluntary. You may choose another way to fulfill these essential requirements.

Step 3

Each directive that applies to your product specifies whether an authorized third party (notified body) must participate in the conformity assessment procedure required for CE marking. This is not mandatory for all products, so it is important to check whether the involvement of a Notified Body is indeed required.
These bodies are authorized by national authorities and officially 'notified' to the Commission andare listed in the NANDO (Notified and Designated New Approach Organisations)database.

Step 4

Testing the product and verifying its compliance with EU legislation (Conformity Assessment Procedure) is the manufacturer's responsibility. One part of the procedure, as a general rule, is risk assessment. By applying the relevant harmonized European standards, you will be able to fulfill the essential legal requirements of the directives.

Step 5

The manufacturer must draw up the technical documentation required by the directive(s) for the assessment of the product's conformity with the applicable requirements as well as for the risk assessment. Together with the EC declaration of conformity, the technical documentation must be submitted upon request by the relevant national authorities.

Step 6

The CE marking must be affixed by the manufacturer or by a representative authorized by him from the EEAor Turkey. It must be affixed to the product or its data label and, in accordance with its legal format, bevisible, legible and indelible. If a notified body was involved in the production control process, it sidentification number is also applied. The manufacturer is responsible for drawing up and signing a "Declaration of Conformity" which proves that the product has been manufactured according to the requirements. It is! Your CE marked product is ready for the market

List of New Approach products and the directives that define their requirements

Active implantable medical devices - Directive 90/385/EEC

Appliances powered by gas fuel - Regulation (EU) 2016/426

Cableways - Regulation (EU) 2016/424

Construction Products Regulation - Regulation (EU) No. 305/2011

Ecodesign requirements for energy-related products - Directive 2009/125/EC

Electromagnetic compatibility - Directive 2014/30/EU

Equipment and protection systems intended for use in potentially explosive atmospheres - Directive 2014/34/EU

Explosives for civil purposes - Directive 2014/28/EU

Efficiency requirements for new hot water heaters with liquid or gas fuel - Directive 92/42/EEC

In vitro diagnostic medical devices - Regulation (EU) 2017/746 and Directive 98/79/EC

Lifts and safety devices for lifts - Directive 2014/33/EU

Electrical equipment intended for use within certain voltage limits - Directive 2014/35/EU

Machinery - Directive 2006/42/EC

Measuring instruments - Directive 2014/32/EU

Medical devices - Directive 93/42/EEC

Noise emissions of facilities intended for use outside buildings - Directive 2000/14/EC

Scales with non-automatic waiting instruments - Directive 2014/31/EU

Personal protective equipment - Regulation (EU) No. 2016/425

Pressure equipment - Directive 2014/68/EU

Pyrotechnic articles - Directive 2013/29/EU

Radio equipment - Directive 2014/53/EU

Recreational crafts and vessels for personal use - Directive 2013/53/EU

Restriction on the use of certain hazardous substances in electrical and electronic equipment - Directive 2011/65/EU

Safety of toys - Directive 2009/48/EC

Simple Pressure Vessels 2014/29/EU (SPVD) - Directive 2014/29/EU

Unmanned aircraft systems and on third-country operators of unmanned aircraft system - Regulation (EU) 2019/945

APPENDIX- Further information on the scope and application of the directives

a) Machinery (Directive 98/37/EC; new Directive 2006/42/EC applicable with effect from December 29, 2009)

SCOPE: Directive 2006/42/EC extends the scope of the established Machinery Directive, as construction site lifts and chuck fasteners as well as other impact machinery will no longer be excluded.

➢ **Machines**

o A device that is equipped or intended to be equipped with a propulsion system other than directly applied human or animal power, consisting of connected parts or components, at least one of which is moving, and which are connected together for a specific application

o the device described in the first subparagraph, lacking only the devices for connection to the place of use or for connection to the sources of energy and drive

o the device described in the first or second subparagraph, ready to be installed and which can function in this state only after it has been installed on a means of transport or installed in a building or structure

o arrangements of machines described in the first, second and third subparagraphs, or partially completed machines, which, in order to achieve the same result, are arranged and operated in such a way as to function as a single unit

o a device of interconnected parts or components of which at least one is moving and which are assembled together to lift loads and the only driving force of which is directly applied human power.

➢ **replaceable equipment**, i.e. a device which, after putting a machine or tractor into operation, is fitted to that machine or that tractor by the operator himself, with the aim of changing its function and/or with the aim of acquiring a new function, insofar as this equipment does not constitute a tool

➢ **protective component** – a component that serves to perform a function related to ensuring safety, which is placed on the market independently, the failure and/or malfunctioning of which endangers the safety of people and which is not necessary for the operation of the machine, or which can be replaced with serviceable parts to keep the machine functioning (e.g. emergency braking devices, seat restraints, rollover protection structures)

➢ **load handling device,** i.e. component or equipment that is not attached to the lifting machine, enabling the load to be held, being placed between the machine and the load or on the load itself, or intended to form an integral part of the load and independently placed on the market; load lifting ropes and their components are also considered load handling devices

➢ **chains, ropes and straps** designed and manufactured for lifting loads as part of lifting machines and load handling devices

➢ a demountable mechanical power transmission device is a demountable component designed to transmit power between a self-propelled machine or tractor and another machine by connecting them to the first fixed power stage.

➢ Partially completed machine, i.e. a device that is almost a machine, but which cannot by itself perform a specific application (eg, a drive system)

EXAMPLES: mini-motorcycles, mobile lift work platforms, electric saws, presses, packaging machines, mobile road construction machines, drilling machines, stone cutting machines, cranes.

DOES NOT INCLUDE: safety features intended for spare parts provided by the manufacturer of the original machine; the special equipment intended for use in fairs and/or amusement parks; machinery specially designed or put into operation for nuclear purposes;

weapons,including firearms; certain vehicles; offshore vessels and mobile installations, as well as the machines installed on board such vessels and/or installations; machinery for military and police purposes; machines for temporary use for research purposes in laboratories; mine ventilation devices; machines designed to move performers during artistic performances; low-voltage equipment (household electrical appliances intended for domestic use, audio and video equipment, information technology equipment, general office machinery, low-voltage switches and controls, electric motors, high-voltage electrical equipment, e.g. switches and controls, transformers.

b) Pressure equipment (Directive 2014/68/EU)
COVERS: equipment subject to a maximum allowable pressure greater than 0.5 bar

EXAMPLES: pressure valves, gas pressure regulators, refrigeration systems and heat pumps, domestic pressure cookers

DOES NOT INCLUDE: pipelines consisting of one or more pipes designed for the conveyance of any liquid or substance from or to an installation (on land or water), including terminal shut-off valves and associated equipment (the exemption does not apply to the standard pressure

equipment in pressure reducing stations or in compressor stations); the networks for water supply, distribution and drainage of water and the facilities for them, such as chutes, water pressure galleries,

pressure shafts for hydroelectric installations and thefacilities for them; simple pressure vessels; aerosol packaging; equipment intended for the operation of vehicles; machines; elevators; low voltage equipment; medical devices;

devices burning gaseous fuels; equipment and protective systems intended for use in potentially explosive atmospheres; weapons, ammunition and military materials;

facilities specially designed for nuclear purposes; control facilities in the exploration and production of oil, gas and geothermal energy, as well as in the mining industry for underground storage, designed to maintain and/or control the pressure in the boreholes;

equipment and machinery with internal spaces for which the sizing, material selection and manufacturing rules are based primarily on requirements for sufficient strength,

resistance and stability to withstand static and dynamic working loads or other operating characteristics and where the pressure does not is a design

factor (eg engines, including turbines and internal combustion engines, steam engines, steam or gas turbines, turbogenerators, compressors, pumps and drives)

; blast furnaces with furnace cooling installations; recuperators, dust collectors; blast furnace gas cleaning installations; kiln-cooled clay pots; gas converters and ladles for melting,

remelting,degassing and casting steel and non-ferrous metals; enclosures of high voltage electricalequipment such as switches, disconnectors, control devices, transformers and rotating machinery; pressure pipes for transmission systems (eg for power supply and telephone cables)

ships, missiles, aircraft and mobile floating equipment, as well as equipment intended for installation on board or for their propulsion; pressure equipment made of elastic casing (eg tires, airbags, game balls, inflatable boats); exhaust and intake mufflers; bottles or cans for aerated drinks intended for final consumption; vessels designed for the transport and distribution of beverages with a PS·V not exceeding 500 bar·L and a maximum permissible

pressure not exceeding 7 bar; facilities covered by ADR, RID, IMDG and the ICAO Convention6; radiators and pipelines in water heating installations; containers for liquids with gas pressure above the liquid up to 0.5 bar.

c) Simple pressure vessels (Directive 2014/29/EU)
INCLUDES: simple series-produced pressure vessels, i.e. any simply welded non-alloy steel, non-alloy aluminum or non-hardenable aluminum alloy vessels subjected to an internal relative pressure greater than 0.5 MPa, which are intended to store air or nitrogen and which shall not be exposed to an open flame. In addition, the vessel is made of:

➢ either by a cylindrical part with a circular section closed with outwardly convex and/or flat bottoms that have the same axis of symmetry as the cylindrical part or by two convexes that have the same symmetry axis;

➢ the maximum working pressure of the vessel must not exceed 30 bar and the product of this pressure by its volume must not exceed 10,000 bar/litre

➢ the minimum operating temperature must not be lower than -50°C and the maximum operating temperature must not be higher than 300°C or steel vessels and 100°C for aluminum or aluminum alloy vessels.

DOES NOT INCLUDE: vessels specially designed for nuclear purposes; vessels intended for installation in vessels or aircraft or for their propulsion; fire extinguishers.

d) **Toys** (Directive 2009/48/EC)

INCLUDES: a product or material designed or clearly intended for play use by children or persons under the age of 14.

EXAMPLES: scooters, dolls, playing cards, balls, finger paints, chemistry experiment kits

DOES NOT INCLUDE: Christmas decorations; detailed scale modelsfor adult collectors; equipment intended for collective use of playgrounds; sports equipment; aquatic equipmentintended for diving in deep water;dolls in folk costumes and decorative dolls, as well as other similar items intended for adult collectors; ''professional'' children's toys placed in publicplaces (shopping centers, train stations, etc.);

puzzles with more than 500 pieces or without a picture, intended for specialists; air rifles and air pistols, fireworks, including checkers; slides and catapults; sets of darts with metal tips; electric ovens, irons or other household goods operating with electricity under normal conditions with a voltage of more than 24 volts; products containing heating ingredients intended for use under the supervision ofadults in training; vehicles with internal combustion engines; children's toys with steam engines; bicycles intended for sport or riding on public highways; video games that can be connected to a video screen operating with a power supply under normal conditions above 24 volts; baby pacifiers, realistic imitation firearms; fashion jewelryfor children.

Due to past problems, in January 2008 the European Commission presented a proposal to improve the safety of toys in Europe. The revision aims to introduce higher safety requirements, strengthen producer and importer responsibility and strengthen market surveillance.

e) **Construction products** (Regulation (EU) No. 305/2011)

COVERS: products manufactured for permanent vendosjen in construction, including both buildings and civil engineering.

EXAMPLES: cement, fire protection and fire alarm systems, radiators, construction lime, roof tiles, chimney bricks, water meters and heat meters, stairs, doors, windows.

f) Electromagnetic compatibility (Directive 2014/30/EU)

COVERS: electrical and electronic appliances, together with their equipment and installations, containing electrical and/or electronic components that may cause electromagnetic interference, and the operation of which may be affected by such interference

EXAMPLES: mobile phones, computers, hi-tech stereos, household appliances, fluorescent lamps, machine tools, switches, navigational instruments

DOES NOT INCLUDE: radio equipment and telecommunication terminal equipment,aviation products, parts and appliances, equipment that cannot generate electromagnetic emissions that exceed the level allowing normal operation of radio and telecommunication equipment and other types of equipment; equipment that works without an unacceptable drop in quality in the presence of electromagnetic interference, which usually occurs as a result of its intended use.

g) Personal protective equipment (PPE, Regulation (EU) No. 2016/425)

INCLUDES: any device or appliance for professional or personal use (e.g. sports, leisure, household) designed to be worn or held by a person to protect against one or more safety hazards (e.g. falls, scrapes, stabs, cuts , bites, noise, heat, fire, electric shock, radiation)

EXAMPLES: respiratory protection, eye protection, protective clothing for professional use (eg gloves, helmets), hearing protectors, high-visibility signaling clothing, mountaineering equipment

DOES NOT INCLUDE: personal protective equipment (PPE) covered by another Directive that has the same objectives as this Directive,PPE designed and manufactured for use by the armed forces or in law and order support (e.g. helmets, shields), PPE for self-defense (e.g.aerosol sprays, self-defense weapons),

PPE designed and developed for personal use against adverse weather conditions (e.g. hats, seasonal clothing, shoes, umbrellas), moisture and water (dishwashing gloves, etc.) and heat (gloves, etc.), PPE intended for the protection or rescue of persons on watercraft or aircraft that are not worn all the time, helmets and visorsintended for drivers of motor vehicles.

h) **Non-automatic weighting instruments** (Directive 2014/31/EU)

SCOPE: a non-automatic (ie, requiring intervention or someone to operate it) measuring instrument that serves to determine the mass of a body, by the earth's gravity on that body. The scale can also serve to determine other mass-related quantities, quantities, parameters or characteristics
The provisions of the Directive relating to essential requirements, conformity assessment and CE marking apply to instruments designed for the following needs:

➢ determination of the table for commercial transactions;

➢ determining the table for calculating a fee, tariff, tax, bonus, fine, reward, compensation or similar type of payments;

➢ determination of the mass with a view to the application of legal prescriptions andexpertise for judicial purposes;

➢ determination of mass in medical practice, i.e. measuring patients for health monitoring,diagnoses and medical treatment;

➢ determination of mass for the purpose of fulfilling prescriptions in pharmacy and determination of weight in analyzes in medical and pharmaceutical laboratories;

➢ setting prices according to weight for direct public sales and in the production of packaged products.

Non-automatic scales designed for other needs must bear the manufacturer's logo or name, as well as information about their maximum capacity.

i) Medical devices

This sector covers about 8,000 types of products, ranging from simple bandages and glasses to life-sustaining implantable devices.

Medical devices (Directive 93/42/EEC)

INCLUDES: medical devices and their related accessories; medical device is any object, used alone or in combination, including the software necessary for its proper application, which is intended by the manufacturer to be used by humans for the following purposes:

➢ diagnosis, prevention, monitoring, treatment or alleviation of a disease state;

➢ diagnosis, monitoring, treatment, relief or balance of injury or disability;

➢ dresearch, replacement or alteration of anatomy or physiological functions;

➢ pregnancy control.

and which do not achieve their primary action in or on the human body by pharmacological or immunological effect or by influencing metabolism, but which may be assisted in their action by such means.

Accessory means an object which is not a device but which is intended by the manufacturer to be used with the device to enable it to be used in accordance with the purpose for which it was designed.

EXAMPLES: disposable medical gloves, glasses, contact lenses, hearing aids, internalorthopedic aids, medical radiation equipment, heart valves.

DOES NOT INCLUDE: in vitro diagnostic devices, active implantable devices, medicinal products for human use, cosmetic products, mixed human blood, blood products, plasma orblood cells of human origin, transplants, tissues or cells of animal origin, unless the productis produced using non-viable animal tissues.

Active implantable medical devices
(Directive 90/385/EEC)

INCLUDES: active medical devices intended to be fully or partially implanted surgically or medically in the human body, or through medical intervention
- in a natural orifice, and which remains there after the procedure. Active is any medical device that functions on the basis of an electrical source,
or any source of energy other than that generated by the human body or gravity.

EXAMPLES: cardiac pacemakers, implantable defibrillators, implantable nerve stimulators, diaphragm stimulators, cochlear implants, implantable
active drug delivery devices.

DOES NOT INCLUDE: medical products for human use, derivatives of human blood, blood products, plasma or blood cells of human origin, transplants
or tissues or cells of animal origin, unless the product is manufactured
using non-viable animal tissues or products ,derived from animal tissue.

In vitro diagnostic medical devices
(Regulation (EU) 2017/746 and Directive 98/79/EC)

COVERS: materials and articles falling within Class 1 of the United Nations Recommendations on the Transport of Dangerous Goods, i.e. explosive substances, explosive preparations, other substances and objects that are produced with the aim of creating a practical explosive or pyrotechnic effect.

INCLUDES: in vitro diagnostic medical devices and their accessories, i.e. products used for the in vitro analysis of tissues and substances (blood, samples) from the human body. The types of analyzes covered are health status, congenital diseases or abnormalities, checking the progress of treatment courses and determining compatibility in case of organ or blood donation.

EXAMPLES: blood grouping products, HIV positivity markers, blood glucose meter.

k) Explosives for civilian use (Directive 2014/28/EU)

l) **Equipment and protective systems f use in potentially explosive atmospheres** (Directive 2014/34/EU)

COVERS:
- equipment (i.e. machines, apparatus stationary or mobile devices, control components and instruments, and protective or protective systems, respectively, which are intended for the generation, transmission, storage, measurement, control and/or conversio of energy and/or handling materials, an which are capable of causing an explosion through their own potential sources of ignition) and

DOES NOT INCLUDE: devices manufactured and used only within the same healthcarefacility, as well as the premises where they were manufactured and the premises in theimmediate vicinity, without having been transferred to another legal site.

j) Devices burning gaseous fuels (Directive 92/42/EEC)

COVERS: gas appliances intended for cooking, heating, hot water production, freezing,lighting and washing, and which have, where applicable, a normal water temperature not exceeding 105 °C. Burners using compressed air,

as well as heating elements equipped with such burners, are also considered appliances. Safety and control devices and subsystems other than compressed air burners and heaters equipped with such burners are also included.

EXAMPLES: gas stoves, domestic cooking appliances, boilers, central heating boilers.

DOES NOT INCLUDE: appliances specially designed for use in an industrial process.

➢ protection systems (i.e. devices which are not part of the equipment as described above, which are intended to terminate the initial explosions immediately and/or to limit the effective range of the explosion and which are marketed separately as stand-alone systems) intended for use in potentially explosive atmospheres (atmospheres that may become explosive due to local and operational conditions).

➢ Safety, control and regulating devices intended for use outside of potentially explosive atmospheres, but necessary for or assisting the safe operation of equipment and protection systems, in view of the risks of explosion.

EXAMPLES: fuel columns, mechanically driven winches and hoists, power-driven winches and elevators, conveyor belts for use in underground installations, fans operating in potentially explosive atmospheres

DOES NOT INCLUDE: medical devices; devices and protection systems used in premises where potentially explosive or chemically unstable substances are stored; equipment intended for use in domestic and non-commercial environments where potentially explosiveatmospheres can occur solely as a result of accidental leakage of gaseous fuel; personal protective equipment, watercraft and mobile marine equipment, certain vehicles (vehicles intended for use in potentially explosive atmospheres are not excluded); weapons,ammunition and war materials.

m) Recreational crafts (Directive 2013/53/EU)

COVERS:

➢ Design and construction of pleasure craft, partially completed craft, other personal watercraft and certain components;

➢ Exhaust gas emissions produced by engines installed on or in recreational and other personal use vessels;

➢ The noise emissions produced by recreational craft with stern engines without an exhaust system or inboard engine configuration, by personal watercraft and by outboard engines and stern engines with an integral exhaust system.

EXAMPLES: starter with protective mechanism for inboard and stern motors, outboard motor starter protection device, rudders, rudder mechanisms and installation cables, fixed fuel tanks and fuel hoses, ready-to-install hatches and marine lights.

DOES NOT INCLUDE: racing watercraft, canoes, kayaks or gondolas, paddleboards; original and one-of-a-kind reproductions of historic vessels; experimental vessels not intended for trade; a vessel built for own use; machinery installed or intended to be installed on such vessels; vessels intended for the carriage of passengers for commercial purposes;submarines; vehicles with airbags; hydrofoils; steam powered vessels with external combustion, coal, coke, wood, oil or gas.

n) Elevators (Directive 2014/33/EU)

INCLUDES: elevators permanently serving buildings and structures,and the safety components used in such elevators. According to the text of the directive, a lift means afacility serving specific levels and having a cabin moving with guides that are fixed fixed and inclined at an angle of not more than 15 degrees to the horizontal, and which are intended for the movement of people, people and goods,only on goods if the cabin is available.

EXAMPLES: devices for locking the doors of the elevator cabins at the landings; anti-fall devices, protecting the cabin from falling or uncontrolled upward movements; speed limiters; shock absorbers; devices in the form of security keys containing electronic components.

DOES NOT INCLUDE: lifting devices with a speed not greater than 0.15 m/s, elevators on construction sites, cable railways, incl. funiculars,lifts specially designed and constructed for military and police purposes,lifts from which work can be carried out, mine lifts, stage lifts, lifts fitted to vehicles, lifts connected to machinery specially designed for access to workplaces , including machine maintenance and inspection stations, racks and pinions, escalators and medical lifts.

o) Radio and telecommunications terminal equipment
(Directive 2014/53/EU)

INCLUDES: radio equipment (a product or component thereof capable of communicating byemitting and/or receiving radio waves using the spectrum allocated for terrestrial/ space radiocommunications) and telecommunications terminal equipment (a product or component thereof designed to connect directly or indirectly to interfaces of public telecommunications networks);
The directive also applies to apparatus which:

➢constitutes a medical device or an active implantable medical device;

➢ is a component or separate technical part of a vehicle.

EXAMPLES: GSM telephone handsets, automatic car door openers, analogue telephones, ISDN terminals, cable and computer modems.

DOES NOT INCLUDE: apparatus for civil protection, defence, state security and criminal law activities, radio equipment used by amateurs(covered when available for public use), marine equipment, wires and cables, radio equipment intended for for use only in the reception of television broadcasting, civil aviation products, equipment and components, airtraffic control equipment.

p) Cableway installations for the transport of people
(Regulation (EU) 2016/424)

INCLUDES: funicular railways or other vehicles in which the function is performed by one or more ropes, rope cabins lifted and/or moved by supporting ropes, including freight cars and lifts, pulling lifts.

DOES NOT INCLUDE: elevators; the trams of traditional construction,driven by cables; equipment used for agricultural purposes; equipment intended for fairgrounds or amusement parks and designed for entertainment purposes; mining facilities and installations for industrial purposes; rope-driven hand rafts; cog railways; chain-driven equipment.

r) Low-voltage equipment (Directive 2014/35/EU)

INCLUDES:water meters, gas meters, volume conversion devices, active electricity meters, heat meters, measuring systems for continuous and dynamic measurement of quantities ofliquids other than water, automatic scales, taxi counters, material measuring devices, parameter measuring instruments, devices to account for gas consumption.

EXAMPLES: household electrical appliances, cable connections for electrical installations,audio, video and other similar electronic systems.

DOES NOT INCLUDE:electrical equipment intended for use in potentially explosive atmospheres, electrical equipment for X-ray and medical purposes, electrical parts for elevators, electricity meters, plugs and sockets for domestic use, control panels for electrical fuses, specialized electrical equipment for marine, aviation or railways in accordance with the safety requirements established by international bodies.

EXAMPLES:air conditioners, general heating circulators, street lighting, refrigerators, computers, televisions, washing machines, vacuum cleaners, copiers.

s) Ecodesign for products using electricity (Directive 2009/125/EC)

INCLUDES:ecodesign requirements for products using electricity, i.e. products which, onceplaced on the market and/or put into use, are dependent on the supply of energy (electricity, solid fuels and rechargeable energy sources) to work as intended, or a product for the production, transmission and measurement of such energy,

including parts dependent on energy supply and intended to be included in energy-using products that are placed on the market and/or in use as individual parts for end users and for which an independent assessment of environmental performance can be made.:

DOES NOT INCLUDE:vehicles for people or goods.

t) Domestic electric refrigerators and freezers
(Commission Regulation (EC) No 643/2009)

INCLUDES: household electric refrigerators, frozen food storage appliances, freezers and combinations thereof.

DOES NOT INCLUDE: appliances that can also use other energy sources (eg batteries, domestic refrigeration appliances that work on the principle of absorption and appliances manufactured to specific specifications).

u) Noise emission from equipment for outdoor use (Directive 2000/14/EC)

INCLUDES: machines which are either self-propelled or which can be moved and which, regardless of the driving elements, are intended for outdoor use and which contribute to the creation of noise in the environment.

Use of equipment in an environment where sound transmission is not significantly affected (eg under awnings, under rain covers or under house framing) is considered outdoor use.

Also included are non-powered equipment for industrial purposes or for environmental applications that are intended for outdoor use and that contribute to the creation of environmental noise.

DOES NOT INCLUDE: non-motorized accessories separately placed on the market or in use (except mechanical concrete breakers and manual breakers), equipment intended for the transport of goods and persons on public roads, railways, air or water, equipment, used by the police or military.

EXAMPLES: brush cutters, compressors, hydraulic breakers, mowers, leaf blowers, trenchers.

v) Ballasts for fluorescent lighting (Commission Regulation (EU) 2019/2020)

INCLUDES: ballasts for fluorescent lighting of central supply.

DOES NOT INCLUDE: ballasts built into lamps, ballasts designed specifically for luminaires to be built into furniture and which form an integral part of the luminaire which cannot be tested separately from the luminaire, ballasts for export from the Community.

x) Boilers for hot water with liquid or gas fuel (Directive 92/42/EEC)

INCLUDES: energy efficiency requirements for liquid or gas fuel hot water boilers with a capacity of not less than 4 kW and not more than 400 kW (standard boilers, low temperature boilers, gas condensing boilers).

DOES NOT INCLUDE:hot water boilers that can be fueled with different fuels (including solid fuels), equipment for instantaneous water heating, boilers designed to be fueled with fuels other than readily available liquid and gaseous fuels (industrial waste gases, biogas ,etc.),

stoves and appliances designed mainly for heating rooms in which they are installed and as a sub-function - providing hot water for central heating and sanitary needs, appliances with a capacity of less than 6 kW, using gravity circulation and designed only for the production and storage of hot water for sanitary needs, boilers manufactured at retail, co-generation systems.

Application 2
Types of conformity assessment bodies
Informative

ISO 17020 Conformity assessment. Requirements for the activity of various types of control bodies;
This standard is applicable to control bodies of type ''A'', ''B''. or ''C'' that are defined in it and applies to each stage of control.

Control stages include design stage, type examination, initial control, in-service control or supervision. The type of control body according to the conditions under which it performs its services and the type of their independence are of the following types:

"A" – carries out control by a third party;
"B" – carries out first-party control and provides control only to the organization of which it is a part, and
"C" – carries out first-party control, second-party control or both types and provides control services to the organization of which it is a part or to other parties, or both.

EN ISO/IEC 17020 is intended for use by control bodies, by accreditation bodies, as well as by other bodies related to the recognition of the competences of control bodies.

The control authorities carry out an assessment of the compliance of the controlled object against the predetermined requirements,

which may be defined in: normative acts, standards, technical specifications, etc.

EN ISO/IEC 17020 is intended for use by control bodies, by accreditation bodies, as well as by other bodies related to the recognition of the competences of control bodies.

The control authorities carry out an assessment of the compliance of the controlled object against the predetermined requirements, which may be defined in: normative acts, standards, technical specifications, etc.

The term "object" for the purposes of this standard includes a product, process, service or facility.

Controlled parameters may include the elements of quantity, quality, safety, usability and security of the object of control.

ISO 17021 Conformity assessment. Requirements to the bodies performing audit and certification of management systems;

The international standard ISO/IEC 17021 contains the principles and requirements for competence, consistency and impartiality of the audit and certification of management systems of all types (e.g. quality management systems or environmental management systems) and for bodies providing these activities.

Certification bodies operating in accordance with this International Standard do not need to offer certification of all types of management systems. Certification of management systems is a third-party conformity assessment activity. The bodies that perform this activity are third-party conformity assessment bodies (called "certification bodies" in this International Standard).

ISO/IEC 17021 is applicable to the auditing and certification of any type of management system. It is accepted that some of the requirements, in particular those related to the competence of the auditors, can be supplemented with more criteria to meet the expectations of the interested parties.

ISO 17025 General requirements for the competence of testing and calibration laboratories;The standard sets out the general requirements for the competence, impartiality and consistency of the work of laboratories and is applied by:

- organizations that have in their structure laboratories performing testing/calibration/sampling, regardless of their size and the number of their personnel;
- competent and regulatory authorities and other organizations;
- customers.

Documents issued by accredited laboratories (protocols, certificates, reports) can be accepted without the need for additional laboratory activities, which is a prerequisite for improving international trade.

Laboratory results are used as a guarantor of the reliability of activities that may have an impact on public trust, health and safety, the environment;

ISO 17065 Conformity assessment. Requirements to the bodies for certification of products, processes and services;

This International Standard contains requirements for the competence, consistency of activities and impartiality of certification bodies for products, processes (production control systems) and services. Certification bodies that work in accordance with the standard do not need to offer all types of certification of products, processes and services.

Certification of products, processes and services is a conformity assessment activity by an independent third party applying certification schemes. Certification schemes are defined in the relevant regulation of the European Commission.

Application 3
OBLIGATIONS OF ECONOMIC OPERATORS

General provisions

Where an importer or distributor places a device on the market under its name or trademarkor modifies a device already placed on the market in such a way that compliance with the requirements of the Regulation may be affected, it is considered a manufacturer and fulfills the manufacturer's obligations .

Each economic operator maintains a register that contains information on each economic operator that has delivered a device to it and on each economic operator to whom he delivered a device.

The information and documents that prove the completed delivery are stored for a period of 10 years after the date of delivery and are provided to the market surveillance authorities upon request.

The specific obligations of manufacturers, importers, authorized representatives and distributors are described in the relevant legal acts for each specific product.

Case Studys

Case Study I: A Leading metal processing company in the Republic of Kosove achieves CE Mark certification

Company X, a well-known company in the metal processing industry in Kosovo, embarked on a strategic initiative to obtain the CE certificate for its products, demonstrating compliance with European Union (EU) standards.

Furthermore, Company X has a presence of over 12 years in the metal processing industry in Kosovo, aiming to expand its products into the European Union market and recognizing the importance of obtaining the CE certificate.

Some of the products of Enterprise X include; Metal structures, cylinders, fences, and metal doors.

Certification Process

a) Identification of harmonized directives and standards

b) Validation of specific product requirements

c) Determination of the need for an independent conformity assessment by an authorized body

d) Product testing and verification of its conformity

e) Preparation and retention of necessary technical information

f) Application of the CE mark on the product and Declaration of Conformity

Company X initiated an in-depth study of EU regulations concerning its product types. This included understanding the Machinery Directive, RoHS (Restriction of Hazardous Substances), and other relevant standards. (Regulation 305/2011 in force since July 1, 2013, replacing CPD 89/106/EC).

- Needs Analysis and Identification of Gaps (GAP Analysis)
- Employee Training and Awareness
- Certification and Training of Welders according to EN ISO 9606-1, 135 P FW FM1 S t10 PB ml.
- Approval of Welding Procedures (WPQR-ISO 15614-1)
- Preparation of Documentation for International Standards EN 3834-2
- Accredited Type A Inspection Body (NDT Testing

After 3 months of careful planning and implementation, Company X successfully obtained the CE certificate for its key product lines. This achievement not only contributed to enhancing the company's reputation for quality and safety but also opened doors to new markets within the European Union, specifically in Germany.

- Welding Coordinator - Implementation and Support of QMS according to ISO 3834-2 and EN 1090-2 EXC3

- Factory Production Control (FPC) and Product Certification for Compliance with EU Standards

- Declaration of Conformity EN1090 0045CPR-1090-1.00XXX.TÜVNO RD. 2018.001

- Collaboration with Certification Organizations

Case Study II: CE Mark certification attained by company Y, a leader in manufacturing of windows.

Company Y, a renowned player in the wood & plastic processing sector in Kosovo, initiated a strategic endeavour to secure the CE certification for its PCV windows, showcasing adherence to European Union (EU) standards.

This case study delineates the journey undertaken by Company Y in pursuit of this certification. With a presence of over 17-year in Kosovo's, Company Y endeavours to penetrate the European Union market, recognizing the pivotal role of obtaining the CE certification.

Among the notable offerings of Company Y are high-quality metal PCV windows, showcasing its commitment to excellence and compliance with international standards.

Certification Process

a) Identifying applicable harmonized directives and standards

b) Validating precise product specifications and requirements

c) Assessing the necessity for an independent conformity evaluation by an authorized entity

d) Conducting comprehensive product testing and confirming adherence to standards

e) Compiling and securely maintaining all essential technical documentation

f) Affixing the CE mark on the product and issuing the Declaration of Conformity

In the process of obtaining CE certification for PCV windows, Company Y utilized a comprehensive array of technical documentation to ensure compliance with relevant standards and regulations.

This documentation included specifications, requirements, and testing methods outlined in various standards such as BDS EN 14351-1:2006+A2:2016 for product performance characteristics, BDS EN ISO 10140-2:2021 for laboratory measurement of sound insulation, and BDS EN ISO 12567-1:2010 for thermal transmittance determination.

Furthermore, standards such as BDS EN 1027:2016 for watertightness testing, BDS EN 1026:2016 for air permeability testing, and BDS EN 12211:2016 for resistance to wind load testing were also referenced.

Additionally, the air permeability classification was determined using BDS EN 12207:2017. Moreover, the acoustical performance of PCV windows was evaluated in accordance with BDS EN ISO 717-1:2021 for airborne sound insulation rating

By adhering to these standards and utilizing the specified testing methods, Company y ensured that its PCV windows met the necessary performance criteria for CE certification.

After 5 months of careful planning and implementation, Company successfully obtained the CE certificate for its key product lines for PVC windows (Profile Schuco).

This achievement not only contributed to enhancing the company's reputation for quality and safety but also opened doors to new markets within the European Union, specifically in Germany.

Case Study III: Company Z Achieves CE Mark Certification as a Leader in Production of Electrical Material.

Company Z, a prominent company in Kosovo's electrical materials manufacturing, embarked on a strategic initiative to obtain CE certification for its products, demonstrating conformity with European Union (EU) standards. This case study focuses on Company's efforts in pursuit of this certification.

With over 25 years of establishment in Kosovo, Company Z aims to expand its market presence into the European Union, recognizing the critical importance of securing CE certification.

Certification Procedure

a) Recognition of relevant harmonized
directives and standards

b) Verification of exact product specifications and requirements

c) Evaluation of the need for an independent conformity assessment by an authorized body

d) Execution of thorough product testing and verification of compliance with standards

e) Compilation and secure storage of essential technical documentation

f) Application of the CE mark to the product and issuance of the Declaration of Conformity

Throughout the process of obtaining CE certification for its flexible conduit system, Company Z meticulously compiled a comprehensive set of technical documentation to ensure meticulous compliance with relevant standards and regulations.

Factory inspections were diligently scheduled during regular working hours, with Company Z generously granting the Certification Body and its inspector's full access to its premises. This facilitated thorough verification of compliance with the stringent requirements outlined in OD CIG 021.
Company Z demonstrated cooperation and transparency throughout the inspection process, ensuring a seamless and efficient assessment.

Production control, monitoring, and routine tests were conducted meticulously, adhering to industry standards such as DIN EN61386-23 (VDE 0605-23):2011-12 and EN 61386:2004 + A11:2010.

By adhering to stringent inspection protocols and maintaining a steadfast commitment to quality and compliance, Company Z underscored its dedication to delivering CE-certified flexible conduit systems of the highest standard.

After careful planning and implementation spanning four months, Company Z achieved the prestigious CE certification for its pivotal product lines, notably for its flexible conduit system.

This significant milestone not only elevated the company's standing for quality and safety but also paved the way for entry into new markets within the European Union, notably Germany.

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Manufacturer's guide for the Application of CE Marking in exporting to the European union

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Ministria e Industrisë, Ndërmarrësisë dhe Tregtisë

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