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PRODUCT CONFORMITY ASSESSMENT AND CE MARKING

Introduction

Manufacturing activities have a long history. Since ancient times people have been making tools and objects that were useful, facilitated certain activities and improved the quality of life. They were often related to agriculture. Over the years, people have moved from using relatively simple tools to objects with increased complexity. They started manufacturing them not only for their own needs but also for the purpose of selling. Thus, craftsmanship was born. Initially, it was only a small-scale activity. Its characteristic feature was that in some area's specialization emerged. A craftsman was a specialist in a particular manufacturing field. As a result, increasingly complex products were made. In the 13th century in Flanders and Italy, the first manufactures were developed where mainly textiles and metal products were produced. The invention of the steam machine revolutionized the approach to production. It resulted in the increase in production capacities. New means of transport were created such as steam locomotives or steam-powered ships. The invention of electricity initiated an intensive period of Industrial Revolution. In 1832, Michael Faraday[1] constructed the first model of an electric motor. In 1879, Thomas Edison[2] built the first light bulb. The turn of the 19th century was a period of intensive technological development. Since then, scientific progress has contributed to the emergence of many inventions and the creation of new products that make many everyday activities more convenient.

The developments in technologies resulted in two basic problems. Firstly, there was a problem with the reliability of devices. For example, the first household refrigerators were produced in 1913[3]. Unfortunately, they were not reliable. Their breakdowns led to the waste of food products that were stored in them. Secondly, they were a source of another problem: they were dangerous. Leaks in refrigeration systems resulted in the release of hazardous substances which were toxic and inflammable. Moreover, servicing the machines that were becoming increasingly common was related with the risk of injury or even death. There was a need for

[1] https://encyklopedia.pwn.pl/haslo/Faraday-Michael;3899905.html (accessed: 21 September 2022).
[2] https://encyklopedia.pwn.pl/haslo/Edison-Thomas-Alva;3896515.html (accessed: 21 September 2022).
[3] https://mediakron.bc.edu/fashiondecor/1913-refrigerator (accessed: 21 September 2022).

the products to be functional, durable, easy to repair and, above all, safe. The intended solution to the problem was a standardization system and legal regulations with regard to the manufacturing of products and their launch on the market.

1. Standardization and legal system

Present day standardization is closely related to the development of electrical devices. In the 1880s, it was realized that the lack of common terminology, measures and assessments slowed down the process of electrotechnical progress. The International Electrical Congress which was convened in St.Louis in 1904 proposed the establishment of a permanent international commission the purpose of which would be to set deadlines and measurements for the assessment of electrical machinery and devices. In 1906 in London, the International Electrotechnical Commission (IEC)[4]was founded which was the first international standardization organization. In subsequent years other organizations were established, including ISO which started its operations at the beginning of 1946. At present it consists of 167 national standardization bodies and has issued 24 492 standards[5].

Numerous standards apply to various types of products; they describe their design features, functions or construction rules to make them not only functional but also safe. However, the existing standardization system does not create legal provisions. The application of standards is, in principle, voluntary. Therefore, if products are to be safe, it is necessary to create legal provisions that would be binding for producers to achieve the assumed goals. Every product must be safe for the users, property and the environment.

In 1958, the European Economic Community (EEC) was established. It was set up by the Treaty of Rome of 25 March 1957. One of its objectives was to provide the basis for the freedom of movement of goods, which required the standardization of regulations, referred to as the harmonization. It assumed the elimination of barriers, e.g. through the recognition of national regulations as nonapplicable. Common rules had to be accepted to guarantee free movement of commodity and goods with the respect to the principles of environmental, consumer and competition protection[6]. To avoid the creation of a multitude of detailed provisions regulating every issue related to product, the principle was to limit to basic requirements, referred to as

[4] https://iec.ch/history (accessed: 21 September 2022.).
[5] https://www.iso.org/store.html (accessed: 21 September 2022.).
[6] https://www.europarl.europa.eu/factsheets/pl/sheet/38/swobodny-przeplyw-towarow (accessed: 21 September 2022).

essential requirements. The adopted directives to the new approach included general framework, i.e. essential requirements necessary to ensure a free movement of goods through the harmonization of regulations. The so-called White Paper from the Commission (1985) defined which technical[7] and physical barriers should be removed and what measures should be taken.

Thus, international law regulations were to become the basis of the product conformity assessment system. On the basis of European law, directives were issued dedicated to particular groups of products which were to be implemented into the legal system of the Member States of EEC, later transformed into the European Union. In this way legal bases were created for several products. It was recognized that essential requirements could be achieved in various ways but the best solution is for manufacturers to use harmonized standards. European Commission and national standardization committees issue lists of harmonized standards. They are assigned to individual directives and regulations described by the conformity assessment system. Their implementation is the basis for the so-called presumption of conformity. It is recognized that products that comply with the standards are also compliant with the essential requirements. In the cases when there are no harmonized standards or they are not used, the presumption of conformity cannot be applied, which however does not exclude the possibility to follow the conformity assessment procedure. The so-called Blue-Guide (the guide concerning the conformity assessment system) assumes the possibility for manufacturers to withdraw from the application of harmonized standard[8], but such attitude is not recommended. The Polish Act on conformity assessment system includes a provision which identifies the purpose of its application which is " to eliminate the threats posed by products to the life and health of users and consumers as well as property and the threats to the environment and to remove technical barriers to trade, to facilitate international trade and create conditions for a reliable assessment of products and their manufacturing processes by competent and independent entities"[9]. However, not all products are covered by the act. This does not mean that other product groups are exempt from any regulations. In this case, one of the most important regulations is the Act on general product safety. As indicated in the act, " it applies to products for which separate provisions do not specify detailed safety requirements"[10].

[7] White Paper from the Commission to the European Council, Brussels 1985, p. 6.
[8] Official Journal of the European Union C272 of 26 June 2016, p. 45.
[9] Act of 30 August 2002 on conformity assessment (Journal of Laws of 2021, item 1344), Chapter 1, Art. 2.
[10] Announcement of 22 January 2021 of the Marshal of the Sejm of the Republic of Poland on the publication of a uniform text of the act on general product safety (Journal of Laws 2021, item 222), chapter 1, Art.2 (1).

The implementation of a mandatory conformity assessment system is the basis for the CE marking of numerous product groups. For example, they include toys i.e. products for children under 14 years of age. Other products include cranes and their safety components, products that are subject to electromagnetic compatibility, machinery, explosives used for civilian purposes, devices operating within particular voltage limits (the range is between 50-1000V AC and 75-1500V DC), measurement devices, recreational watercraft and jet skis, personal protective equipment, pressure equipment, simple pressure vessels, radio equipment, appliances burning gaseous fuels, construction products, cableway equipment, medical devices, pyrotechnic products and systems intended for use in potentially explosive atmosphere. Even in the cases when a product does not belong to any of the above groups, the implementation of RoHS directive on the restriction of hazardous substances in electrical and electronic equipment should be considered. This may concern torches, for example.

It is the responsibility of manufacturers to identify all the directives and regulations that apply to their products and then to follow the rules therein. Legal acts should be read carefully in order to be able to follow them correctly. More than one conformity assessment path is usually available to manufactures. There are often doubts which path should be taken and whether the product is always subject to a mandatory certification. This is a crucial issue for the management organizations as it concerns the responsibility for their product. Launching products on the market that have not been subjects to conformity assessment and do not meet the requirements may result in serious consequences. One should remember that the market is subject to surveillance by entities appointed by state authorities. This fact is most often forgotten by importers from outside the EU. The Customs Office is entitled to supervise the conformity of products imported to the EU market. Even if such products are not subjected to control in the customs area, they may be identified as noncompliant by other supervision authorities such as PIP (the National Labor Inspectorate) in the case of machinery and devices used in companies or by PIH (the State Trade Inspectorate) when the products are launched on the consumer market. Medical devices are an extreme example of responsibility imposed on business entities. A distributor which launches on the market a product that does not meet the requirements described in the Act[11] is subject to a fine of up to PLN 250,000 while a fine for a manufacturer of medical devices may be as high as PLN 5 million. It is important to note that these are administrative fines.

[11] Act of 7 April 2022 on medical devices (Journal of Laws, 2022, item 974).

2. Product conformity assessment

In order to identify properly the applicable directions and regulations, it is necessary to conduct a detailed analysis of the product itself. The association of the type of product with the title of the legal act should not be taken into consideration as the scope of its application is defined within the directive or regulation. The scope may differ from the one assumed initially by the manufacturer. For example, slicers for bread or sausages may be associated with the need to use the directive on machinery. However, it is stated in the Directive that *household appliances intended for domestic use* are excluded from the scope of the Directive[12]. Therefore, the need to apply this directive or exclude it from application depends on the declared use of the product by the manufacturer. In the case of household appliances such a product will be subject of directive 2014/30/EU (electromagnetic compatibility – EMC), directive 2014/25/EU (shortly referred to as the LVD or low voltage directive), directive 2011/65/EU (RoHs) and also to the directive on the waste electrical and electronic equipment (WEEE). The WEEE Directive does not lead to the CE marking. The user is informed about its use by a symbol of a crossed-out garbage bin usually placed on the nameplate. This information is crucial as such products cannot be utilized together with municipal waste and are subject to electro-waste collection. The identification process is not always easy to conduct. The European Commission issued various guidebooks with tips that can be used by manufacturers. For some time, it has also been necessary to check whether a particular group of products has not been covered by regulations on energy efficiency. Consumers are aware of efficiency labels that are placed on many white goods, but the list of products is much more extensive. For example, it includes external power suppliers which have a defined level of power consumption in no-load state as well as at the 25, 50, 75 and 100% load of the rated power. Such tests will probably be performed to verify the conformity with the requirements when a sample of a marketed product is taken by a market surveillance authority.

The next step should include the identification of the applicable harmonized standards. They are presented in the European Commission Internet service[13] and in the list of the Polish Standardization Committee (PKN) [14]. The standards can be purchased in a printed version or in the form of electronic files. They can also be borrowed for 30 minutes on the PKN website[15].

[12] Directive 2006/42/EC of the European Parliament and of the Council of Europe of 17May 2006 on machinery, and amending Directive 96/16/EC, Art 1 (2).
[13] https://single-market-economy.ec.europa.eu/single-market/european-standards/harmonised-standards_en (accessed: 21 September 2022).
[14] https://www.pkn.pl/polskie-normy/dyrektywy-rozporzadzenia-i-normy (accessed: 21 September 2022).
[15] https://sklep.pkn.pl/ (accessed: 21 September 2022).

There are also reading rooms where standards are available free of charge. Borrowing standards or using a reading room may be useful before making a decision on buying selected documents. Only legal copies should be used.

Apart from technical harmonized standards there are also sector standards the use of which may be useful when designing products or even recommended when there are no harmonized standards for a given product or construction feature or when the existing standards have not been harmonized yet. There is a high degree of probability for the manufacturers who adopt technical solutions based on standards that their product will meet the security standards. Therefore, the analysis of standardized requirements should be taken into consideration already in conceptual work and during the product design stage. Manufacturers occasionally identify standards only after developing a prototype and the introduction of changes at this stage of product development may be expensive and time consuming. The knowledge of standards does not only help to learn the construction requirements but also to find out what tests the product should undergo. Independent consultants sometimes inform manufacturers that any research is not necessary. However, in such cases the statement of compliance with the standard will not be supported by any objective evidence and the manufacturer will be exposed to the risk of launching products that do not meet the requirements or even are dangerous. The savings made in this way do not always pay off.

The conformity assessment process should include the development of the product technical documentation. The required content of documentation is given in particular directives. If a product is subject to more than one directive, the documentation requirements may vary. In such cases, a compilation of all the articles of the directives and regulations must be performed. Technical documentation must be archived for a period time specified in the directive beginning after the production and launching processes were completed. However, if products are still being manufactured, the technical documentation should be updated. The alterations may result from changes in the construction features, the use of other materials, parts, components as well as from changes in regulations and standards. The parts of documentation that are removed should be archived. Increasingly, there is a requirement to perform a risk analysis to help the prevention of undesirable events. The manufacturer predicts the occurrence of various possible adverse situations. In the case of the above-mentioned external power suppliers, potential hazards include internal sparking, a short circuit, high temperature and fire, which may cause the housing of a power supplier to ignite. This should be counteracted by the use of inflammable housings. The manufacturer has two options: either

to obtain from the supplier of the housings a certificate of inflammability or to order tests in an independent laboratory. Observations of the market show that this parameter is often neglected. The above example shows to people responsible for managing organizations that many number of factors must be considered. Every decision must be preceded by detailed analyses.

Apart from external tests, manufacturers should work out procedures concerning the surveillance of the manufacturing, interoperational and final control processes. Only the products that are checked in line with the accepted procedures can be released for sale. Final controls do not involve the necessity to check every single product. This is often impossible due to the mass volume of production or the fact that the control of every product would deprive them of essential features. It is impossible to check whether a single-use fuse is working properly without bursting it. In the case of products for which adequate degree of cleanliness must be ensured before hermetic packaging, the final control cannot determine if the microbiological requirements have been fulfilled. Therefore, designing appropriate manufacturing processes is crucial to achieve this target. This is done through validation tests which are frequently used for the validation of manufacturing processes, machinery or complete technological lines. Statistically selected product samples can be then checked at predetermined times. Obviously, the samples should be taken in an appropriate way; for example the samples for the assessment of microbiological cleanliness should be picked considering hygiene (e.g. with the use of protective gloves and face masks), placed in a sterile bag and transported with the principles of cleanliness[16]. Thus, product conformity assessment should also apply to production and inspection processes whose schedule should be a part of the product technical documentation.

User manual is an important appendix to technical documentation. The manual should include a clear description of the intended use of the product, methods of its use, any contraindications, safety information and warnings. Moreover, directives and regulations provide detailed descriptions of the requirements. Manuals must be supervised. For this purpose, they should have identification features that make it possible to distinguish between current and historic versions.

The product conformity assessment involves the concept of product certification. Not every product that is subject to conformity assessment and marked with the CE graphic symbol

[16] A. Szałek, L. Madej-Kiełbik, *Wybrane metody oceny kontroli jakości wyrobu gotowego,* „Technologia i Jakość Wyrobów" No. 66, Sieć Badawcza Łukasiewicz – Instytut Biopolimerów i Włókien Chemicznych, Łódź 2021, p. 29.

CE must be subject to the certification process. Product certification is one of the conformity assessment paths which may sometimes be implemented optionally but in other cases may be mandatory. As a rule, certification is applied for products that are dangerous or the ones that require independent confirmation of safety and effectiveness. Certification processes apply to several medical, pressure and gas fuel devices. The necessity to use this path of conformity assessment is implied by directives. If it has to be applied, the manufacturer selects a product certification body which is designated to assess the conformity of a particular group of products. The body is notified by a superior authority which certifies its competences and supervises its activities. The aim of a such a supervision system is to ensure high effectiveness of all activities related to products. The certification body inspects technical documentation, visits the production site and confirms the compliance of the completed process with the specified requirements. This does not relive the manufacturers of their duties. The manufacturer must be prepared to the certification process before applying to the notified body. Having confirmed the conformity, the certification body issues a certificate of conformity for a period of 5 years. In this period, the manufacturer is supervised by the certifying body and after the conformity certificate expires, the manufacturer may apply for the extension of its validity for another similar period. If the product is not subject to mandatory certification, this step may be omitted. Manufacturers must remember that they are obliged to implement internal production control the purpose of which is to ensure the compliance of each manufactured product with the product that has been assessed, tested or certified.

The final step in the conformity assessment process is the issuance of a declaration of conformity by the manufacturer, which is done under his sole responsibility. The declaration of conformity is the manager's declaration that the product meets the requirements. Therefore, it is legally binding. The declaration is sometimes just an appendix to technical documentation but for some products it must be provided together with them. This, for example, is the case of machinery subject to Directive 2006/42/EC. Such product features as the name, type, model, number or series number must be identical both in the declaration and on the product. Any discrepancies will be to the disadvantage of the manufacturer. A product marked with CE sign must bear the symbol and in justified cases, when this is impossible, the marking is placed on the packaging. Appropriate proportions and minimum labeling should be maintained. For small products, the symbol may not be smaller than 5 mm.

Manufacturers sometimes make errors in the CE symbol: it has incorrect proportions, the crossbar in the letter E is not shortened, or there is incorrect distance between the two letters which have to fit into two overlapping circles.

There is a certain „myth" concerning wrong proportions in the marking. Some experts started referring to the CE symbol as *China Export*. There is no justification for doing so. Chinese manufacturers can affix the correct CE marking without any problems. The fake marking is not justified by the Chinese marking system; it simply does not exist. It seems that the term *China Export* was developed as a joke but in time it started to be treated seriously by some auditors of certifying bodies who inform about it during their trainings and by quality consultants who use it in reference to incorrect CE marking without any justification. This myth should be busted once and for all. In the reply to the question of a member of EP on CE marking, the European Parliament in the *Parliamentary question P-5938/2007 ASW* stated that "the Commission is aware that there exists the misconception attributing CE marking the meaning 'Chinese export'. The Commission is not aware of the existence of a 'China export mark' but considers that the mark refers to the CE marking as foreseen in the European legislation without, however, respecting the dimensions and proportions prescribed therein"[17]. The answer also informed that the Commission was in constant discussions to ensure that Chinese exporters respect EU regulations for products exported to EU. Unfortunately, false information is still reproduced on numerous websites and their authors copy it uncritically without checking its reliability and thinking about the justification for using different marks. People working in the area of conformity assessment should particularly understand the need to be guided by facts only.

Conclusions

Ensuring an adequate level of product quality is an important responsibility area of manufacturers, their authorized representatives, distributors and importers. Product safety must be ensured throughout its whole lifecycle. Presently, a high level of product reliability has been achieved, especially in comparison with the products that were produced previously. Nevertheless, there is still space for improvement. The standardization system develops new standards the implementation of which increases the certainty of achieving an appropriate safety

[17] https://www.europarl.europa.eu/doceo/document/P-6-2007-5938-ASW_EN.html (accessed: 21 September 2022).

level. Legal regulations refer to the implementation of standards, which results in stating the compliance with the essential requirements. Manufacturers are obliged to follow the legally established conformity assessment paths for their products.

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Abstract

There is a close correlation between the conformity assessment system and standardization. The implementation of harmonized standards leads to the presumption of conformity. The issue has legal bases which ensure the surveillance of the launch of products that are considered safe. CE marking is the confirmation of the conformity assessment in which the manufacturer declares that his products meet the substantial requirements of directives and regulations. This is of crucial significance for shaping product quality.

Key words

Product conformity assessment, standardization, CE mark, China Export, product safety, certification.