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PRACA DOKTORSKA

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**BADANIA I ANALIZA RYZYK
W PROCESIE WPROWADZANIA WYROBU NA RYNEK
W UJĘCIU WYMAGAŃ TECHNICZNYCH**

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DOCTORAL THESIS
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RESEARCH AND ANALYSIS OF RISKS IN THE PROCESS OF INTRODUCING A PRODUCT TO THE MARKET
IN THE TERMS OF TECHNICAL REQUIREMENTS

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Abstract

Following dissertation raise the subject of functioning of European Product Conformity Assessment System. The aim of the dissertation was to demonstrate the importance of actions taken by the notified body in the process of reducing the risk associated with placing on the market and non-comply product. The results of the analyses and research included in the dissertation include statistical data from national market surveillance authorities, information from the System for Dangerous Non-Food Products - RAPEX and data obtained from the Notified Body No. 2703 in the scope of voluntary and regulated activities. An in-depth analysis of selected certification processes was carried out, with the criterion of compliance of which were legal acts, i.e. Directives: 2006/42/EC; 2014/53/EU; 2014/34/EU. The most common non-conformities with the essential requirements for a given product were distinguished and presented in numerical terms.

The work consists of six chapters, which address the following issues:

- chapter 1 – presents an analysis of the history of the European Product Conformity Assessment System, including a description of the reasons for its creation, the evolution towards the integration of national mechanisms of the EU country members, initially operating independently, the gradual elimination of legal barriers and unification into one legal mechanism operating on the basis of the same principles;
- chapter 2 – presents an analysis of the current legal and organizational status of the European Product Conformity Assessment System. It takes into account the main legal acts from the level of the European Commission and their implementation into national regulations, using Poland as an example. Characterize the procedure for obtaining the status of a notified body by the applicant, and the concept of so-called voluntary certification, in order to indicate differences from certification in the regulated area conducted by notified bodies.
- chapter 3 – presents an analysis of the activities of notified bodies and their role in the European System for Conformity Assessment of Products, legal basis and criteria for assessing competences for notified bodies, together with the procedure for applying for accreditation, ending with obtaining authorization by the national authorizing body and entry into the database of notified bodies of the European Commission – NANDO.
- chapter 4 – presents an analysis of the principles of functioning of notified bodies, gives an example of organization and management relating to the examined entity Notified Body No. 2703 and undertakes an analysis of risks related to the introduction to the market of products covered by Directives 2006/42/EC, 2014/53/EU, 2014/34/EU.
- chapter 5 – presents an analysis of the principles of introducing products to the market, the responsibility of the entity responsible for the above, the structure of market surveillance with a distinction of individual bodies in the scope of their responsibility and the place and role of the notified body in market surveillance of products.
- chapter 6 – presents the results of research and analyses concerning the product conformity assessment process in the European Union in terms of the impact of the participation of a notified body on the level of risk related to meeting product requirements by demonstrating, on the basis of descriptive and numerical data obtained from available databases of market surveillance authorities and data on the activities of Notified Body No. 2703, indicating the most common non-conformities at the stage of certification activities.

The dissertation ends with a summary and formulated conclusions. The conclusions presented in the dissertation are the result of research and analyses of legal documents, available literature, statistical data of state market surveillance authorities included in available databases, information obtained in the scope of in-depth interviews with employees of Notified Body No. 2703 participating in the certification processes presented in the work (Chapter 6) and the results of research on the certification activities of Notified Body No. 2703. The dissertation demonstrates the significant impact of the notified body on reducing the risk related with placing the product to the market.