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CONFORMITY ASSESSMENT SYSTEM FOR PRODUCTS – POWER EQUIPMENT: METHODOLOGICAL APPROACH AND PRACTICAL APPLICATION

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Abstract. This article presents a structured methodology for the internal conformity assessment of power equipment, developed and applied within TOOLSWORLD – Bulgaria. The study addresses the regulatory framework of the European Union, including the Machinery Directive, Low Voltage Directive, Electromagnetic Compatibility Directive, RoHS Directive, and Regulation (EU) 2019/1020, and emphasizes the dual role of conformity assessment as both a legal requirement and a strategic tool for risk and quality management. A six-stage methodology is proposed, encompassing documentation collection, verification, cross-referencing with product lists, data extraction, classification into five conformity categories (Cat.1 – Cat.5), and visualization of results. Applied to a portfolio of 482 products, the methodology revealed that nearly half (47.1%) of the products were in partial conformity (Cat.2), while only 4.8% achieved full conformity (Cat.1). The results highlight critical compliance risks, particularly products with expired or missing documentation (Cat.4 and Cat.5), and underline the importance of systematic document management. The study contributes to both practice and academia by bridging regulatory requirements with practical implementation, offering a replicable model for internal conformity systems that can enhance risk management, audit readiness, and market surveillance.

Keywords: Conformity assessment; European Union directives; risk management; product compliance; internal audit; quality management; market surveillance; certification; power equipment; technical regulation

1. Introduction

In the context of the modern global economy, the free movement of goods is inextricably linked to strict requirements for safety, quality, and environmental

compliance (European Commission, 2022). The European Union has established the legal framework for this process through directives and regulations that introduce common principles of conformity assessment, starting with the "New Approach" of 1985 and later reinforced by the New Legislative Framework of 2008 (NIST, 2022). This framework facilitates trade by eliminating technical barriers and ensures that products placed on the market meet the essential requirements for the protection of health, safety, and the environment (European Commission, 2022).

Key legislative acts include the Machinery Directive (2006/42/EC) (European Parliament & Council, 2006), the Low Voltage Directive (2014/35/EU), the Electromagnetic Compatibility Directive (2014/30/EU) (NIST, 2022), the Restriction of Hazardous Substances Directive (2011/65/EU – RoHS) (NIST, 2022), as well as the horizontal Regulation (EU) 2019/1020 on market surveillance and product compliance (European Parliament & Council, 2019). These acts define the obligations of manufacturers, importers, and distributors (i.e., economic operators) (European Commission, 2022), as well as the tools available to national authorities to exercise market control. At the core of all requirements lies the obligation to provide a Declaration of Conformity (DoC), supported by technical documentation – certificates, test reports, and evidence of harmonized standards applied (NIST, 2022). In practice, however, the process of collecting, verifying, and systematizing this documentation is often challenging. The reasons may vary:

– large number of products in the company's portfolio;
– variety of formats and languages of the documents;
– uncertainty regarding applicable directives and standards;
– lack of standardized internal procedures for classification and control.

These challenges are also highlighted in the scientific literature on conformity assessment, which notes difficulties with systematically identifying requirements, unclear responsibilities, and diverse practices within large organizations (Vasara & Kivistö-Rahnasto, 2015).

As a result, it is not uncommon to encounter situations where certain product models fall outside the scope of presented certificates, available documents have expired, or the information is incomplete. Such cases pose not only regulatory and legal risks but also economic consequences, including halted sales, product recalls, or sanctions by supervisory authorities. Moreover, according to EU market surveillance practice, noncompliant products represent not only a safety threat to consumers but also a source of unfair competition (Mjakuškina & Lapiņa, 2018).

In this context, there arises a need to develop a systematic and transparent approach to internal conformity assessment that ensures comprehensive checks and traceability of results. This article presents such a system, implemented within the company TOOLSWORLD – Bulgaria. It combines legislative requirements with a practical methodology for verifying documentation, systematizing data in a digital environment, and classifying products according to their level of compliance.

The main goal is to demonstrate how a well-structured internal system can serve simultaneously as a risk management tool and as preparation for external audits or inspections. In doing so, the system contributes both to increased trust in product quality and to the effective functioning of the internal market (Liepiņa, Lapiņa, & Mazais, 2014).

2. Theoretical Framework

2.1 Regulatory Basis

Conformity assessment is a central instrument of the European technical regulatory system. It represents the process through which it is demonstrated that a product complies with the applicable requirements before being placed on the market. The European Union applies the so-called New Approach in legislation (introduced with the Council Resolution of 1985) and the updated New Legislative Framework of 2008, which introduced the principles of harmonized regulation (NIST, 2022). According to this approach:

– Directives set out essential requirements for safety and protection (of health, the environment, etc.) without providing technical details (European Commission, 2022).

– The application of harmonized standards creates a presumption of conformity with these requirements (NIST, 2022).

– Evidence of compliance is provided through a Declaration of Conformity by the manufacturer and/or certificates issued by notified bodies, where required by the relevant directive (European Commission, 2022).

Key directives and regulations concerning technical products (including power tools and equipment) include the Machinery Directive 2006/42/EC (European Parliament & Council, 2006), the Low Voltage Directive 2014/35/EU and the Electromagnetic Compatibility Directive 2014/30/EU (NIST, 2022), the RoHS Directive 2011/65/EU (NIST, 2022), and Regulation (EU) 2019/1020 on market surveillance (European Parliament & Council, 2019). This regulatory framework ensures equal conditions for manufacturers and a high level of consumer protection while safeguarding public interests such as health, safety, and environmental protection, as well as fair competition in the internal market (European Commission, 2022).

At the same time, it presents challenges for companies, which must manage and document the conformity of broad and diverse product portfolios. This requires continuous monitoring of amendments to directives and standards and maintaining up-to-date documentation.

2.2 Role of Conformity Documents

Certificates of conformity and technical test reports are the primary evidence demonstrating the application of specific standards and confirming that the product has undergone the necessary checks. The quality and completeness of

the documentation are decisive for accurate conformity assessment. In practice, common problems include variations in format and language, lack of translation into a comprehensible language, incomplete model designations, or expired certificates. Such shortcomings create the risk of formal non-conformity – where the product may technically comply with requirements but lacks sufficient documentary evidence.

2.3 Practical Challenges

The scientific and expert literature (e.g., in the fields of market surveillance and metrology) highlights several major challenges in applying conformity assessment within companies:

– Fragmentation of processes (absence of a unified internal system for managing documents and requirements) (Vasara & Kivistö-Rahnasto, 2015).

– Dynamic regulatory base (frequent updates to directives, regulations, and standards that businesses must follow).

– Significant resource burden, particularly for companies with large product assortments.

– Dependence on external information providers – manufacturers or importers supplying the necessary documents.

These problems manifest across global supply chains and require new approaches to ensure compliance (Marucheck, Greis, Mena, & Cai, 2011). Developing a structured methodology for systematic internal verification is therefore essential to ensure reliability, transparency, and efficiency in the process. Such a methodology should include mechanisms for collecting, verifying, comparing, and classifying documents, while also providing traceability and easy visualization of results.

2.4 Significance for Scientific and Practical Fields

The theoretical framework highlights the dual nature of conformity assessment. On the one hand, it is a legal requirement, aimed at ensuring compliance with regulatory standards and preventing unsafe or nonconforming products from entering the market. This explains why the EU adopted the New Legislative Framework in 2008 to enhance product safety and the quality of conformity assessment (European Commission, 2022). Noncompliance leads to sanctions and restricted market access. On the other hand, conformity assessment is a strategic tool for risk and quality management. It helps companies build trust among consumers and partners by guaranteeing that only verified and reliable products reach the market (Liepiņa, Lapiņa, & Mazais, 2014). Conformity is closely linked to quality management – for example, integrating conformity assessment into quality systems has been shown to contribute to the market release of compliant and safe products (Liepiņa et al., 2014).

This study builds on these principles and aims to propose a practical system for internal assessment that addresses the aforementioned challenges and integrates theoretical requirements into a functional organizational model. In this way, it

contributes both to practice (by demonstrating a real-world approach to ensuring compliance) and to the academic field (by exploring the relationship between regulatory requirements and quality management).

3. Methodology

The conformity assessment methodology applied to power equipment follows a structured workflow that integrates both managerial and expert responsibilities. Unlike a purely documentary process, this methodology starts with the product manager and then involves expert verification. The stages are as follows:

Step 1 – Product Proposal – Each potential product in the category of power equipment is initially proposed by the product manager. The product's main characteristics (e.g., voltage, power rating, application) are recorded in the internal product database.

Step 2 – Determination of Regulatory Scope The expert evaluates to which European directives and regulations the product belongs. For power equipment, these typically include the Low Voltage Directive (2014/35/EU), the Electromagnetic Compatibility Directive (2014/30/EU), the RoHS Directive (2011/65/EU), and, in some cases, the Machinery Directive (2006/42/EC). In the compliance matrix, each directive is marked either as "Applicable" or "N/A" if the product does not fall under its scope.

Step 3 – Request for Documentation. Once the applicable scope is defined, the product manager requests from the manufacturer or supplier the necessary documentation, which includes EU Declarations of Conformity (DoC), type-examination certificates (where required), and technical test reports.

Step 4 – Expert Verification Upon receipt, the expert performs a detailed assessment of the documents: verification of certificate validity (issue/expiry date, issuing body accreditation), consistency between product models listed in the certificate and those in the portfolio, compliance with harmonized standards (e.g., EN 60204-1 for electrical equipment of machines, EN 55014 and EN 61000 for EMC).

Step 5 – Classification into Conformity Categories

Based on the results of verification, each product is classified into one of five categories as shown on Table 1:

Table 1. Category description of products according to the conformity compliance

Category	Description
Category 1	the item has got all necessary certificates and TR
Category 2	the item has got all certificates and TR for main Directives, and ROHS but chemical reports PAH, SCCP/POP, REACH are missing or issued for not final color.
Category 3	the item has got certificates and TR for main Directives, but missing chemical reports ROHS, PAH, SCCP/POP, REACH.
Category 4	the item has got not all certificates and TR for main Directives and chemical reports ROHS, PAH, SCCP.
Category 5	missing certificates and TR

Step 6 – Recording and Traceability All results are documented in the compliance matrix. Non-applicable directives are marked as "N/A," while applicable ones are filled with the product's conformity status. This ensures traceability and allows the company to generate transparent compliance reports for audits and inspections.

4. Results

The described methodology was experimentally applied to a portfolio of 482 products (mainly handheld power tools and related equipment) of TOOLSWORLD – Bulgaria. After collecting and verifying the documentation, the products were classified according to the categories Cat.1 – Cat.5. The resulting distribution provides a clear indication of the overall state of conformity within the company shown on Figure 1.

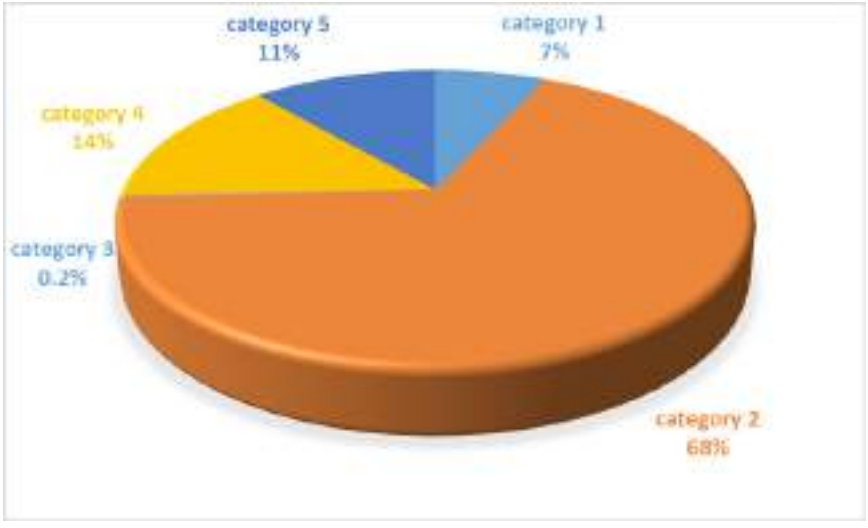

Figure 1. Distribution of categories of power eqipment

Cat.1 (Full Conformity): Only 4.8% of products (23 items) fall into this category, meaning they have fully valid and applicable certificates explicitly covering the model. These are most often new products with recently issued documentation or products from established suppliers with strict compliance policies.

Cat.2 (Partial Conformity): The largest share – 47.1% (227 products) – belongs to this group. Typically, these cases involve certificates or reports that do not cover all product variations. For example, a certificate issued for a base model while the company also sells modified versions (e.g., different colors or accessories) not explicitly listed. Although technically compliant, the documentation reveals a gap that requires attention.

Cat.3 (Incomplete Documentation): A negligible share – only 0.2% (1 product) – falls into this category. Such cases involve presented documents missing essential information, such as absent signatures, dates, or listed standards. This signals the need for clarification from the supplier.

Cat.4 (Nonconforming Document): About 10% of products (48 items) were found to have formally noncompliant documentation, most often due to expired certificates. This represents a serious risk, as these products are present on the market without valid proof of conformity.

Cat.5 (No Documents): 7.9% of products (38 items) lacked any documentation proving conformity. These were mainly older models or items from suppliers who failed to provide certificates. Such products pose the highest risk and require urgent measures (e.g., suspension of sales, document requests, or independent testing).

Outside the Scope of CE Marking: Interestingly, 13 products (2.7%) were identified as not subject to CE marking (e.g., spare parts or consumables). This revealed initial misclassification, as they were wrongly included in the conformity scope.

The overall distribution shows that the main compliance risk for the product portfolio is not the complete absence of documentation, but rather the limited coverage of certificates relative to the diversity of models (Cat.2). In other words, the "devil is in the details" – a large part of the documentation exists but is not fully aligned with each specific product (Vasara & Kivistö-Rahnasto, 2015; Marucheck, Greis, Mena, & Cai, 2011).

5. Discussions

The analysis highlights three main findings. First, the largest share of products (47.1%) falls into Category 2 (partial conformity). This shows that the main risk is not a total absence of documentation, but incomplete coverage of product chemical reports. Second, the very small share of Category 1 (full conformity, 4.8%) indicates that complete compliance remains an exception. This underlines the need for stricter internal procedures, such as timely requests for renewed certificates and systematic monitoring of model coverage. Third, products in Categories 4 and 5 (17.9% combined) represent the highest regulatory and business risk, as they are either backed by invalid documentation or lack evidence of conformity altogether. These cases require urgent corrective measures, such as halting sales until valid documents are provided. The proposed classification system demonstrates three clear advantages:

– Transparency – management can instantly see the compliance status of the portfolio.

– Prioritization – critical categories (4 and 5) are addressed first.

– Audit readiness – standardized documentation facilitates inspections and external audits.

Despite these benefits, limitations persist. The methodology depends on the quality of supplier documents and on expert interpretation in cases of inconsistent product designations. Furthermore, evolving EU legislation requires periodic updates of criteria. Future improvements should focus on automation (OCR/AI) for certificate analysis and ERP integration for real-time linkage of products and documentation. In summary, the results confirm that the main weaknesses of conformity assessment arise not from regulatory gaps but from its practical implementation and document management.

6. Conclusions and summary

The conformity assessment system for power equipment developed in this study offers a structured and transparent approach that aligns EU regulatory requirements

with practical company needs. Applied to 482 products, the methodology demonstrated its effectiveness in identifying risks, with the majority of issues linked to partial conformity (Category 2) and invalid or missing documents (Categories 4 and 5).

By combining systematic documentation checks, clear categorization, and traceability, the system enhances risk management, supports audit readiness, and provides a reliable basis for corrective actions. Its further development should prioritize automation and integration with digital tools to increase efficiency and ensure continuous compliance in a dynamic regulatory environment.

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