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CONFORMITY ASSESSMENT OF PERSONAL PROTECTIVE EQUIPMENT: A METHODOLOGICAL FRAMEWORK AND PRACTICAL APPLICATION

Dr. Victor Arsov, Assist. Prof.
University of Chemical Technology and Metallurgy (Bulgaria)
Dr. Marieta Yancheva-Popova, Assoc. Prof.,
Dr. Desislava Koleva, Assist. Prof.
Technical University of Sofia, (Bulgaria)

Abstract. This article proposes a structured internal conformity assessment methodology tailored to Personal Protective Equipment (PPE) and applied within TOOLSWORLD – Bulgaria. Building on a previously validated system for power equipment, the approach translates EU legal requirements into an operational workflow for documentation collection, expert verification, traceability, and risk-based categorization of products into five compliance categories (Cat.1 – Cat.5). The regulatory basis centers on Regulation (EU) 2016/425 on PPE, complemented by the New Legislative Framework guidance ("Blue Guide" 2022) and the horizontal market-surveillance regime in Regulation (EU) 2019/1020. The framework operationalizes presumption of conformity via harmonized standards (e.g., EN ISO 21420, EN ISO 13688, EN 166, EN 149, EN 388), while also accounting for chemical-safety obligations relevant to materials (e.g., REACH Annex XVII PAHs; POPs restrictions on SCCPs) where applicable. The study contributes a replicable model for companies managing diverse PPE portfolios, aligning regulatory compliance with practical risk management and audit readiness. It also situates the method within broader literature on conformity assessment and supply-chain assurance for protective equipment.

Keywords: Conformity assessment; Personal protective equipment (PPE Regulation (EU) 2016/425; Harmonized standards (EN ISO 21420, EN 388, EN 149)

1. Introduction

The free movement of goods in the EU hinges on robust product-safety rules grounded in the New Legislative Framework (NLF). The Commission's 2022 Blue Guide consolidates these cross-sector principles, clarifying obligations for economic operators, the role of harmonized standards, and the interface with

market-surveillance authorities (European Commission, 2022). In the PPE domain, these horizontal principles are instantiated by sectoral legislation that requires clear technical documentation, EU Declarations of Conformity (DoC), and – where relevant – intervention by notified bodies.

For PPE specifically, Regulation (EU) 2016/425 defines the legal framework covering design and manufacture, classification by risk, conformity-assessment routes (Modules A, B, C/C2, D), and CE-marking rules, with presumption of conformity supported by harmonized standards published in the Official Journal (European Parliament & Council, 2016). The regime is enforced in the field through the horizontal market-surveillance system of Regulation (EU) 2019/1020, ensuring that only compliant and correctly documented PPE circulates on the internal market (European Parliament & Council, 2019).

At the firm level, translating these requirements into daily practice is non-trivial: portfolios often span multiple PPE categories (I – III) and standards families; documents arrive in heterogeneous formats and languages; and suppliers' certificates may be incomplete, expired, or misaligned with exact model designations. These practical frictions mirror challenges reported in the wider compliance and operations literature, especially for globally sourced protective equipment where documentation quality and counterfeit risks have been recurrent issues (Marucheck, Greis, Mena, & Cai, 2011; Vasara & Kivistö-Rahnasto, 2015).

To address these gaps, we adapt an internal conformity system previously applied to power equipment – centered on systematic document collection, expert verification against legal/standard references, and five-tier categorization (Cat.1 – Cat.5) – to the specificities of PPE. The aim is a transparent, repeatable workflow that supports risk prioritization, seamless audit trails, and proactive market-surveillance readiness.

2. Regulatory Framework for PPE

2.1. Legal Basis and Scope

Regulation (EU) 2016/425 is the primary act governing PPE. It sets essential health and safety requirements (Annex II), defines obligations for manufacturers, importers, and distributors, and classifies PPE into three risk categories (I, II, III). The Regulation links presumption of conformity to harmonized standards referenced in the Official Journal and specifies CE-marking rules, including the notified body's identification number for Category III PPE (European Parliament & Council 2016).

2.2. Conformity-Assessment Routes

Article 19 maps risk categories to conformity-assessment procedures: Category I follows internal production control (Module A); Category II requires EU type-examination (Module B) plus conformity to type (Module C); Category III requires Module B and, in addition, either Module C2 (supervised product checks

at random intervals) or Module D (quality assurance of production process). These routes operationalize third-party involvement proportionate to risk, with technical documentation retained and DoCs kept available to authorities (European Parliament & Council, 2016).

2.3 Harmonized Standards Landscape

Presumption of conformity is achieved by applying harmonized EN/EN ISO standards cited under the PPE Regulation. Cross-cutting "general requirements" include EN ISO 21420 for protective gloves (which supersedes EN 420) and EN ISO 13688 for protective clothing – both used alongside product-specific standards (e.g., EN 166 for eye protection; EN 149 for filtering half masks; EN 388 for mechanical risks for gloves). These standards define performance, testing, and marking that underpin compliant design and labeling (European Commission, 2022; ISO, 2012; ISO, 2017).

2.4 Horizontal and Complementary Rules

PPE placed on the market is also subject to the EU's market-surveillance regime under Regulation (EU) 2019/1020, which strengthens coordination among authorities and controls for products entering the EU (European Parliament & Council, 2019). In exceptional situations (e.g., COVID-19), the Commission has issued targeted recommendations to ensure lawful placing on the market while guarding against falsified documentation – reinforcing the primacy of the standard PPE conformity routes in ordinary conditions (European Commission, 2022).

2.5 Chemical Safety

While many PPE are not electrical/electronic and thus outside RoHS, materials may still trigger chemical restrictions – e.g., REACH Annex XVII limits on polycyclic aromatic hydrocarbons (PAHs) in parts with prolonged skin contact, or short-chain chlorinated paraffins (SCCPs) restrictions under the POPs Regulation (EU) 2019/1021. Companies frequently request PAH/SCCP/REACH test reports to complement PPE files, particularly for gloves, footwear, or polymer components with direct dermal exposure (European Parliament & Council, 2019; European Parliament & Council, 2016).

3. Methodology

The conformity assessment methodology for PPE adapts the structured workflow previously validated for power equipment portfolios to the specific legal and technical requirements of Regulation (EU) 2016/425. It integrates both managerial and expert tasks, ensuring systematic documentation, traceability, and risk-based categorization.

Step 1 – Product Proposal. Each prospective PPE item (e.g., gloves, safety glasses, helmets, respirators) is proposed by the product manager. Core attributes (type of protection, intended use, risk category under Regulation (EU) 2016/425) are entered into the internal product database.

Step 2 – Determination of Regulatory Scope. The conformity expert maps the product to relevant EU legal obligations: PPE Regulation (EU) 2016/425 (mandatory for all items); Regulation (EU) 2019/1020 on market surveillance; and complementary chemical restrictions (e.g., REACH Annex XVII, POPs).

Step 3 – Request for Documentation. The product manager requests: EU Declaration of Conformity (DoC); EU Type-Examination Certificate (Module B), where applicable; Surveillance evidence for Cat. III PPE (Module C2 or D); Technical test reports (harmonized EN/EN ISO standards); Chemical test reports, when relevant.

Step 4 – Expert Verification. The expert checks: Validity (issue/expiry dates, notified body accreditation); Model consistency; Standards compliance; Completeness (signatures, references).

Step 5 – Classification into Conformity Categories. Each PPE item is assigned to one of five categories, shown on table 1:

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

Category	Description
Category 1	DoC, Type-Examination Certificate (if applicable), and supporting test/chemical reports are valid and complete.
Category 2	Core PPE certificates present, but complementary chemical reports missing or incomplete.
Category 3	Certificates present but with administrative gaps (missing signatures, incomplete references).
Category 4	Certificates expired or referencing obsolete standards.
Category 5	No DoC, certificates, or test reports provided.

Step 6 – Recording and Traceability. All results are stored in a digital compliance matrix, ensuring traceability and facilitating audit readiness.

4. Results

The six-step conformity assessment methodology was applied to TOOLSWORLD – Bulgaria's portfolio of **256 PPE items**. Each product was classified into one of the five conformity categories (Cat.1 – Cat.5). The resulting distribution is presented in Table 2 Total PPE items assessed: 256

Table 2. Distribution of PPE products by conformity category

Category	Description	Count	Percentage
Cat. 1 (Full Conformity)	*All valid DoC, EU Type-Examination Certificate (if applicable), and supporting reports.*	*49*	***19.1%***
Cat. 2 (Partial Conformity)	*DoC and Type-Examination Certificate available, but complementary chemical reports (e.g., PAH, SCCP, REACH) missing or incomplete.*	*99*	***38.7%***
Cat. 3 (Incomplete Documentation)	*Documentation present but containing administrative gaps (e.g., missing signature, incomplete references).*	*12*	***4.7%***
Cat. 4 (Invalid/Expired Documents)	*Certificates expired or referencing obsolete standards.*	*2*	***0.8%***
Cat. 5 (No Documents)	*No DoC, certificates, or test reports provided.*	*2*	***0.8%***

5. Discussions

The distribution of PPE products across the five conformity categories reveals several critical insights. Modern approaches to conformity assessment increasingly emphasize risk-based internal controls, which align with findings reported in the literature (Aven, 2016). These weaknesses in EU-level surveillance systems are further evidenced by the European Court of Auditors, which notes that product-safety controls remain insufficiently robust (European Court of Auditors, 2020).

First, the largest share of items (38.7%) falls under Category 2 (partial conformity). This confirms that the most frequent compliance gap is the absence of complementary chemical reports (e.g., PAH, SCCP, REACH), despite the presence of valid DoCs and Type-Examination Certificates. Similar findings are reported in conformity-assessment

literature, where incomplete documentation rather than technical non-conformity is identified as the primary weakness (Vasara & Kivistö-Rahnasto, 2015; Marucheck et al., 2011).

Second, only 19.1% of PPE products achieved full conformity (Category 1). This relatively low proportion indicates that complete and up-to-date documentation remains the exception. EU market-surveillance practice has repeatedly highlighted expired or outdated PPE certificates as a recurrent issue, particularly since EU Type-Examination Certificates are valid only for five years (European Parliament & Council, 2016).

Third, although Categories 4 and 5 represent just 0.8% each of the portfolio, they carry disproportionately high risk. Products with expired or missing certificates may not lawfully be placed on the EU market, exposing companies to potential sales suspensions, recalls, or penalties (Mjakuškina & Lapiņa, 2018). Even isolated cases in these categories undermine consumer trust and create unfair competition.

Finally, Category 3 (4.7%) shows that administrative errors (e.g., unsigned DoCs, missing standard references) are not negligible. While less severe than expired or missing certificates, they still require corrective action to avoid formal non-conformity during audits.

Overall, the results reinforce that the weakest link in PPE conformity is document management, not product performance. By strengthening internal procedures – such as systematic monitoring of certificate expiry dates and periodic requests for updated chemical reports – companies can substantially reduce compliance risks and improve audit readiness.

6. Conclusions and summary

The conformity assessment of PPE within TOOLSWORLD – Bulgaria shows that partial conformity (38.7%) is the most common compliance gap, mainly due to missing chemical reports, while only 19.1% of products achieved full conformity. The highest risks, though rare (0.8% each), are products with expired or missing certificates. Strengthening documentation management and monitoring certificate validity remain the key priorities for ensuring compliance, audit readiness, and consumer safety.

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✉ **Dr. Victor Arsov, Assist. Prof.**
University of Chemical Technology and Metallurgy
Sofia, Bulgaria
E-mail: v.arsov@uctm.edu

✉ **Dr. Marieta Yancheva-Popova, Assoc. Prof.**
ORCID iD: 0009-0003-4335-8029
WoS ResearcherID: ODM-2671-2025
Technical University of Sofia
Sofia, Bulgaria
E-mail: myancheva@tu-sofia.bg

✉ **Dr. Desislava Koleva, Assist. Prof.**
Technical University of Sofia
Sofia, Bulgaria
E-mail: koleva_ds@tu-sofia.bg