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Research Article

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Ways to Address the Unification of Medical Equipment Certification Systems in the UK, EU, and UA

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Abstract

A seemingly simple task—assessing the suitability of a given piece of medical equipment for use in healthcare—evolves into a complex and critical challenge when it involves a comprehensive evaluation, often in quantitative numerical terms, of both the harm and benefit to human health and the environment posed by each human-made device across the entire spectrum of its impact.

"... everything is poison, and everything is remedy..." (Paracelsus). The knowledge available to people in well-established areas of efficiency and safety assessment is formalized into standards and regulations. These are used by experts who are also professionally equipped with knowledge of potential environmental hazards associated with the use of the device. Experts may conduct various experiments and assess their outcomes. Although this process may seem straightforward, the main challenge lies not in the quantitative assessment of certain indicators, but in determining how to account for ALL significant harmful factors and their correlations with the beneficial effects of a particular device.

To address this issue, the authors propose the use of logical procedures—a methodology of automatic formal assessment—to serve as a theoretical evaluation preceding experimental research.

When analyzing medical equipment assessment procedures in the United Kingdom, the European Union, and Ukraine, with the aim of developing unified evaluation methods for these countries, the authors recommend the application of a logical formal assessment procedure. This proposal seeks to reduce the influence of subjective expert judgement in favor of a formal and objective assessment of the entire body of existing knowledge on the subject at a given point in time.

The proposed procedure for assessing the suitability of equipment for medical use does not exclude the experimental verification of particular conclusions. Rather, it introduces a formal theoretical evaluation process that can shorten both the current theoretical assessment procedures and the necessary volume of experimentation required to validate the formal theoretical evaluation. This is particularly important when assessments span a wide range of knowledge domains.

The focus of the article is on the provability of conclusions and the role of evidence as a driving force in the scientific development of industrially significant intellectual fields.

Keywords: Medical Equipment Certification, Regulatory Harmonization, Conformity Assessment, International Collaboration, Axiomatic Method

1. Introduction

The certification of medical devices in the United Kingdom, the European Union, and Ukraine is governed by different legal frameworks, which significantly impact the process of market access in each region.

2. Comparison of Certification Procedures in Three Jurisdictions

In the EU, Regulation (EU) 2017/745 (MDR) came fully into force in 2021, replacing previous directives and introducing unified and stricter requirements for CE marking and conformity assessment [1]. Following Brexit, the United Kingdom continues to apply the Medical Devices Regulations 2002 (UK MDR 2002), which transpose the former EU directives (90/385/EEC, 93/42/EEC, 98/79/EC) into UK law [2]. At the same time, regulatory authorities such as the MHRA have introduced the new UKCA marking to replace the CE mark, although CE-marked devices remain acceptable on the UK market during the transition period, which has been extended until 30 June 2030 [3]. In Ukraine, the certification system is based on national technical regulations adopted in 2013 (e.g., Cabinet of Ministers Resolution No. 753/2013), harmonised with the former EU directives [4]. Since July 2015, a separate conformity assessment procedure has been required for market access in Ukraine, and possession of a CE certificate issued in the EU is not sufficient on its own [5]. Legislative changes introduced in 2019 allow recognition of MDR/IVDR certificates under specific conditions, indicating a move toward harmonisation of regulatory requirements [6].

Despite the shared goal of ensuring product safety and efficacy, key differences exist in conformity requirements, market surveillance, and post-market monitoring systems. The EU has implemented more rigorous conformity assessment procedures (e.g., enhanced clinical data requirements and the unique device identification system) with centralised oversight through designated Notified Bodies and the EUDAMED database [7]. The UK retains a system based on the previous regulatory framework, with oversight by the MHRA and UK Approved Bodies; however, Northern Ireland continues to apply EU regulations under the Northern Ireland Protocol [8]. New post-market surveillance rules to be introduced in the UK in 2025 aim to improve incident tracking and response times [9]. In Ukraine, manufacturers are required to undergo local conformity assessments and appoint an Authorised Representative who communicates with national regulatory bodies [10]. Although Ukraine's post-market surveillance system is harmonised with the former EU requirements, it remains under development. This necessitates management of discrepancies in classification criteria and documentation requirements when recognising EU certificates [11].

These regulatory divergences pose significant challenges for medical device manufacturers, who must meet the requirements of multiple markets simultaneously. This often results in duplicated testing and the preparation of additional documentation [12]. Inconsistencies in classification criteria and technical documentation requirements—especially when comparing the new EU MDR with older frameworks—further complicate global market access strategies [13]. These differences contribute to the so-called "time lag" in the release of medical devices, leading to delays in patient access to innovative technologies and reduced competitiveness for manufacturers in the global market [14].

There is therefore a pressing need to improve and optimise existing certification systems to facilitate international market access. Harmonisation of regulatory requirements can streamline global trade, reduce costs associated with duplicate conformity assessments, and accelerate the market introduction of innovative medical devices [15]. Recent measures, such as the extension of CE certificate validity in the UK [3] and the recognition of EU certificates in Ukraine [6], represent practical steps toward reducing regulatory barriers. International collaboration—such as through the International Medical Device Regulators Forum (IMDRF)—is contributing to the convergence of standards and practices [16]. Joint efforts toward global unification of certification requirements will help establish a more efficient and predictable oversight system that maintains a high standard of safety and fosters innovation in medical technologies.

A comparative analysis of medical device certification systems in the UK, EU, and Ukraine highlights the importance of global cooperation and regulatory harmonisation. Despite legislative and procedural differences, the shared objectives of public health protection and innovation support are common to all regions. A transition toward internationally harmonised requirements and stronger collaboration among regulatory authorities will reduce barriers for manufacturers and ensure timely access to essential medical technologies [15].

Medical device certification plays a key role in ensuring patient safety and the efficacy of medical technologies. Proper certification guarantees that devices meet strict quality and safety standards designed to protect public health [17]. In the context of globalization and rapid technological advancement, manufacturers must adapt their products to meet varying regulatory requirements—a particularly pressing issue for companies seeking to enter international markets.

In the United Kingdom, Brexit has brought substantial changes to the regulatory landscape, leading to the introduction of new requirements and the UKCA marking for medical devices intended for the domestic market [18]. At the same time, CE certificates remain valid on the UK market during the transition period, creating additional challenges for manufacturers operating in both the UK and European markets [19].

In the European Union, the regulation of medical devices is governed by Regulation (EU) 2017/745, which establishes uniform standards and conformity assessment procedures across the EU. While this approach ensures a high level of safety, the certification process requires significant time and resource investment, especially for high-risk devices [20].

Ukraine, following the European model, has developed its own certification system based on national technical regulations. The conformity assessment process in Ukraine includes the mandatory appointment of an Authorized Representative and the local completion of certification procedures. While similar to the EU system, it retains specific national characteristics [21].

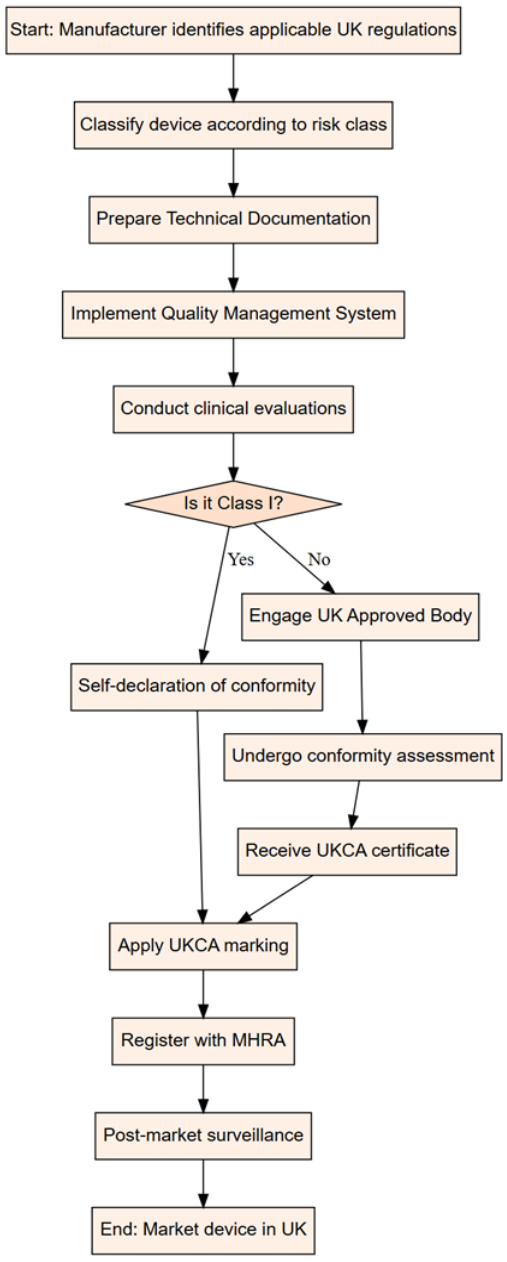
3. Certification Processes in Each Jurisdiction

3.1. United Kingdom

In the United Kingdom, the regulation of medical devices is carried out in accordance with national legislation based on the UK Medical Devices Regulations 2002 (as amended), considering the requirements arising from Brexit. For foreign manufacturers, it is mandatory to appoint a "Responsible Person" based in the UK, who is responsible for registering devices with the Medicines and Healthcare products Regulatory Agency (MHRA) and maintaining all necessary technical and regulatory documentation [22].

For high-risk devices, conformity assessment is conducted with the involvement of approved bodies, while for low-risk devices, a self-assessment procedure is permitted [23]. Upon successful completion of the audit and confirmation of conformity, the UKCA marking is issued, which is required for placing devices on the UK market [24].

In addition, the post-market surveillance system provides for regular oversight, including incident monitoring and corrective actions, thereby ensuring continuous compliance with safety standards [25].

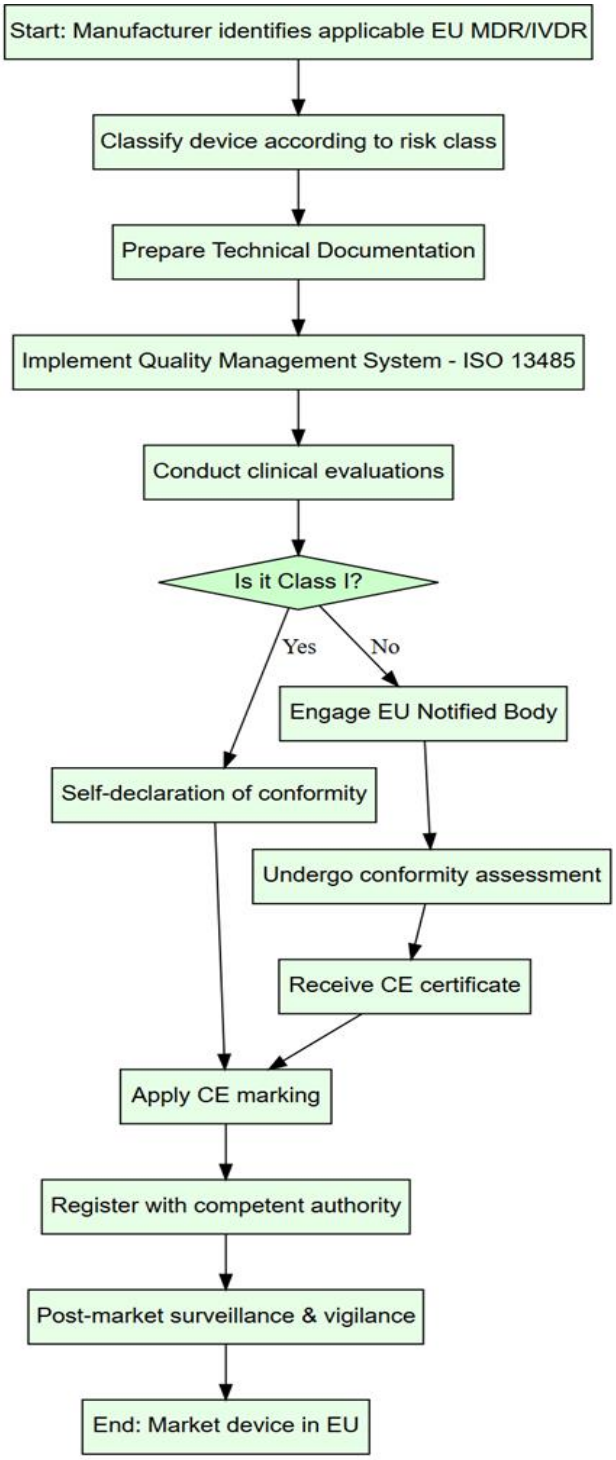


3.2. European Union

In the European Union, the certification of medical devices is regulated by Regulation (EU) 2017/745 (MDR), which established uniform requirements for conformity assessment across the entire EU territory [26]. Devices are classified according to risk level, as defined in the annexes to the regulation, and for Class II and III devices, the involvement of Notified Bodies in the conformity assessment procedure is mandatory [27].

The certification process includes the preparation of extensive technical documentation, the conduct of a clinical evaluation, and the implementation of a post-market surveillance system, all of which ensure high standards of safety and performance [28].

The successful completion of this procedure results in the issuance of the CE marking, which allows the devices to circulate freely and be marketed throughout the EU [29].

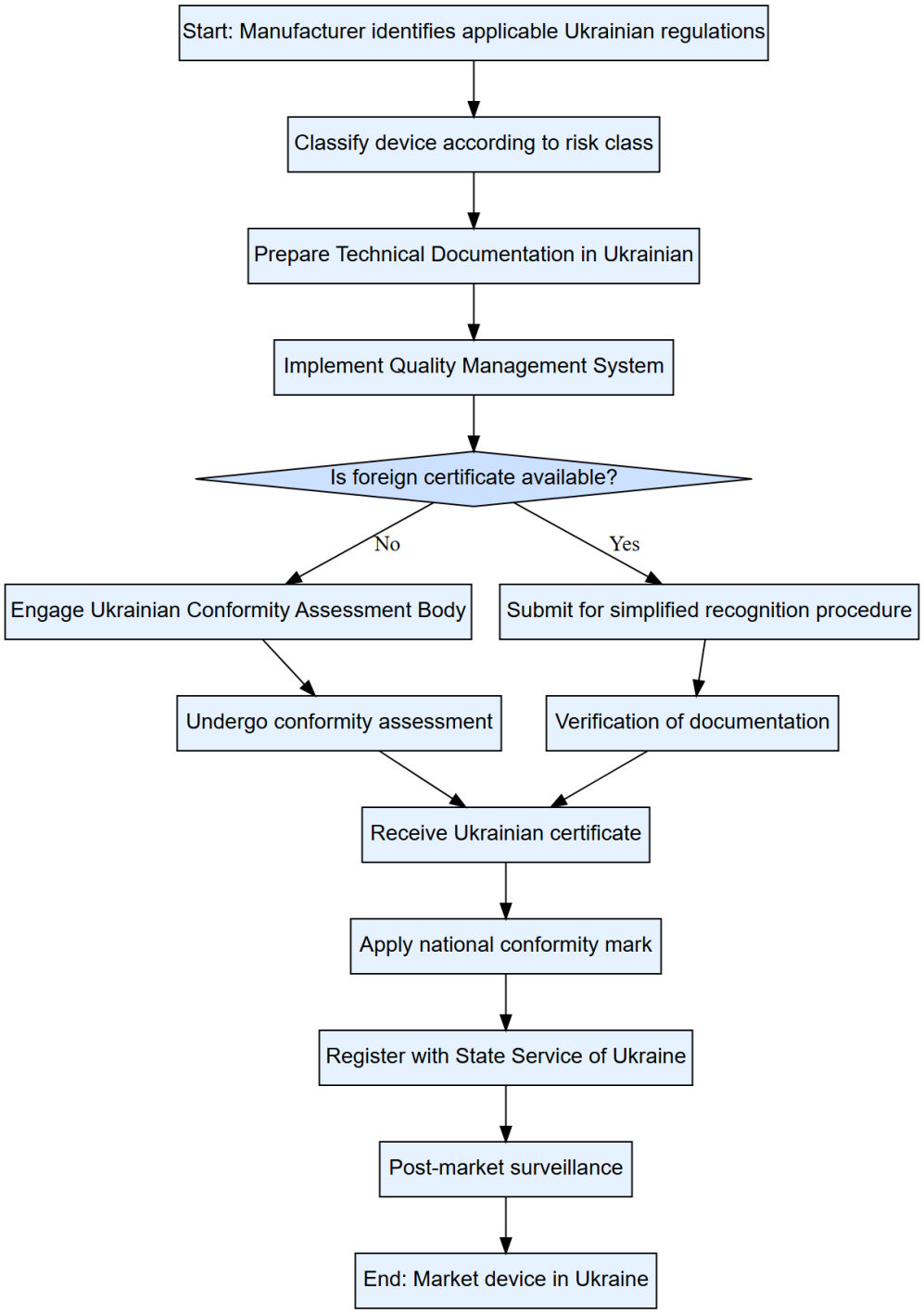


3.3. Ukraine

In Ukraine, the medical device certification system is based on national technical regulations, such as Cabinet of Ministers Resolution No. 753/2013, and is aligned with European standards [30]. Conformity assessment is carried out through national bodies operating in a manner similar to the EU's Notified Bodies; however, for low-risk devices, a self-declaration of conformity procedure is permitted [31].

Foreign manufacturers are required to appoint an Authorised Representative in Ukraine, who is responsible for liaising with the State Service of Ukraine on Medicines and Medical Devices and for registering the products [32].

Additionally, Ukraine applies a batch certification procedure for specific groups of devices, which facilitates faster market entry. However, certain exceptions apply, particularly for sterile devices [33].



4. Comparative Analysis of Certification Processes

This section presents a detailed comparative analysis of medical device certification processes in the United Kingdom, the European Union, and Ukraine. The analysis covers the following aspects: overview of certification bodies, conformity assessment procedures, cost and timeframes, as well as key challenges and differences.

4.1. Overview of Certification Bodies

In the United Kingdom, medical device certification is carried out by Approved Bodies designated under national regulations. Foreign manufacturers are required to appoint a Responsible Person who liaises with the MHRA and ensures product registration [34]. In the EU, certification is conducted through Notified Bodies operating under the unified Regulation (EU) 2017/745, which ensures a consistent approach to conformity assessment across the entire Union [35]. In Ukraine, conformity assessment is performed by national bodies accredited under ISO/IEC standards. Foreign manufacturers must appoint an Authorised Representative, which ensures adaptation to local requirements [36].

4.2. Conformity Assessment Procedures

In both the UK and the EU, the conformity assessment procedure includes an audit of the quality management system, review of technical documentation, and—for Class II and III devices—a clinical evaluation with the involvement of Notified Bodies [37]. In the EU, this procedure is strictly regulated, and successful completion leads to the issuance of a CE certificate [35]. In Ukraine, the procedures are similar to those in the EU: low-risk devices may undergo self-declaration, while high-risk devices require assessment by national bodies. In certain cases, batch certification may be used to accelerate market entry [38]. However, differences in audit methodology and documentation requirements may impose additional time and financial burdens on manufacturers operating across multiple markets [39].

4.3. Cost and Timeframes

Certification in the EU and the UK entails significant financial investment due to the cost of audits, preparation of technical documentation, consultancy services, and maintenance of post-market surveillance systems [40]. In Ukraine, costs may be somewhat lower; however, manufacturers must undergo local certification, incurring additional expenses for translation and documentation in the Ukrainian language [41]. The average certification timeline in the EU is approximately eight months. In the UK, timeframes are comparable, considering the transitional periods, while in Ukraine, the duration depends on the selected procedure (self-declaration or assessment by authorised bodies) [42].

4.4. Key Challenges and Differences

The analysis reveal that the main challenges lie in regulatory complexity and the need to adapt to the diverse requirements of each market. Manufacturers seeking to operate simultaneously in the UK, EU, and Ukraine must comply with both UKCA and CE marking, as well as meet specific documentation requirements, including language and local adaptations [43]. The choice of certification body also plays a critical role, as variations in qualification, timelines, and audit costs can significantly impact the overall efficiency of the certification process [44]. These differences create additional barriers to international market entry and increase risks for manufacturers [45].

5. Advantages and Disadvantages of Each Certification Process

5.1. United Kingdom

Advantages:

- The system based on UK MDR 2002 offers a certain degree of flexibility, allowing self-assessment procedures for low-risk devices [46].
- The requirement for a Responsible Person for foreign manufacturers facilitates effective communication with the MHRA and ensures compliance with regulatory requirements [46].

Disadvantages:

- The post-Brexit transition, involving the need to obtain both UKCA marking and CE conformity, leads to additional administrative and time-related burdens [47].
- Uncertainty regarding future regulatory changes may cause delays in the certification process [47].

5.2. European Union

Advantages:

- The unified regulatory framework under Regulation (EU) 2017/745 ensures high safety standards through stringent requirements for clinical evaluation and post-market surveillance [48].
- Harmonised regulatory requirements allow CE-marked devices to circulate freely among EU Member States [48].

Disadvantages:

- The certification procedure for Class II and III devices entails substantial financial and time investments, along with the need for extensive technical documentation [49].
- Strict demands for clinical data and supporting documentation may pose significant barriers for small and medium-sized enterprises [49].

5.3. Ukraine

Advantages:

- Ukraine's certification system largely draws from the European model, facilitating adaptation for manufacturers already familiar with EU standards [50].
- Self-assessment procedures are permitted for low-risk devices, and batch certification is available to expedite market entry [50].

Disadvantages:

- The need to prepare documentation in Ukrainian and appoint an Authorised Representative introduces additional administrative barriers for foreign manufacturers [51].

- Differences in technical documentation requirements and audit methodologies between the Ukrainian and EU systems can lead to delays and added costs [51].
- Inconsistencies in the performance of national conformity assessment bodies increase the risk of untimely certificate issuance [52].

5.4. Comparative Discussion

Overall, the analysis shows that each system has its own strengths and weaknesses.

In the United Kingdom, the system provides a degree of flexibility for low-risk devices, but the dual compliance requirements (UKCA and CE) complicate processes for manufacturers operating internationally [46–47].

In the EU, the unified regulation ensures a high level of safety, but the certification process remains complex and resource-intensive, which disproportionately affects innovative devices and small enterprises [48–49].

Ukraine, while aiming for harmonisation with European standards, still faces local administrative and documentation barriers, which may hinder and prolong the certification process for foreign manufacturers [50–52].

Thus, optimisation and unification of regulatory requirements at the global level appear essential to reduce administrative burdens, lower costs, and accelerate the market entry of new medical devices [52].

6. Approaches to Solving the Problem

Article Objective:

This study has examined the certification procedures for medical equipment in the United Kingdom, the EU, and Ukraine. These procedures must embody sufficient clinical, scientific, and technical competence to evaluate the specific technologies embodied in the proposed medical equipment for which they are intended. The development of a modern evaluation methodology requires the integration of current scientific capabilities, particularly those expressed through high-level artificial intelligence systems.

The task of AI in the context of safety is not only to solve the problem itself but also to create an automated process for verifying the safety of the resulting solution for both humans and the environment. In essence, this concerns the automatic formal proof of the truthfulness—or "satisfactory solution or TRUTH"—in terms of the acceptability of the solution from all perspectives regarding its impact on related processes. Accordingly, each of these perspectives must be considered, and their full range must be incorporated to the greatest extent possible.

But how can this list of dependent processes and areas of influence be defined to ensure maximum accuracy or truth of the practical solution? How can a single formal task encompass diverse, sometimes contradictory or unrelated factors that affect both humans and the environment through the use of medical equipment?

The authors find it particularly relevant to explore these questions as critical elements in addressing the stated problem.

6.1. Potential for Formalizing Regulatory Procedures

The logical approach to modelling practical tasks involving such competencies—determining the most suitable evaluation methods and the forms of cooperation among authorised bodies to assess the safety and appropriateness of specific medical devices—has, in the authors' view, significant potential. This approach can simplify the approval process while also providing a formal evaluation of justification.

Such a method is capable of integrating existing assessment procedures in the three discussed jurisdictions and of constructing a certification process that satisfies all three systems' requirements. The process of unification can be organized according to the principles proposed by the authors, enhancing the precision of safety assessments for medical equipment to the highest possible level, based on the following rationale:

Scientific knowledge and new scientific ideas must serve as tools for foresight in order to justify their costs. Mere observation and recording of phenomena are not enough. Today, AI seeks to substitute humans across entire sectors, not only replicating standardized procedures but also generating solutions to specific tasks [53]. Ensuring AI's safety for human use has become a challenge for the scientific community. Though there are growing restrictions and requirements for its use these alone are insufficient [54]. Scientific ideas must be purposefully oriented toward improving the human environment. Hence, problem-solving outcomes must be truthful and based on verified facts to avoid misleading people.

The primary criterion for scientific proposals is that if they are truly scientific, they must arise from facts, rely on facts, and be confirmed by facts. The method of proof must not distort initial data but must yield true conclusions that correspond to human reality. Facts lead to proofs. The pursuit of proof and the emphasis on provability are the driving forces of scientific progress and define successful research activity. Science draws its strength from verified knowledge.

6.2. The Substantive and Formal in the Theory of Knowledge

The concept of the American philosopher of science Thomas Kuhn on the phases of scientific development in the world community declares a constant change of two qualitatively different periods - the period of "normal science" and the "revolutionary" period [55].

The period of "normal science" is the period of the undivided dominance of one or another, so-called, "scientific paradigm", that is, a certain model of scientific activity, consisting of a set of theoretical principles, methodological norms, ideological attitudes, value criteria. This period is characterized by extensive accumulation, expansion of scientific solutions arising from the logical and methodological model generally accepted in the scientific community. A kind of expansion of the dominant paradigm occurs. But such

a "peaceful" conquest of the "space" of problems studied by science is not infinite. The triumphant march of explanatory, paradigm-commenting statements eventually encounters a serious obstacle: within the framework of the initial set of ideas, more and more exceptions to the accepted rules gradually accumulate, i.e. problems that are fundamentally unsolvable within the framework of the old paradigm.

A crisis, or "revolutionary" period, arises. The search for alternative ideas and paradigms based on them begins. A struggle, competition, arises between the proposed concepts, as a result of which one of the new paradigms wins, which means the beginning of a new period of "normal" science. Then this entire cycle is repeated.

T. Kuhn's model of scientific development allows us to analyze one very important aspect of cognition - the dialectic of the substantive and the formal in the process of comprehending the truth.

Thomas Kuhn believes that the "explosive" transition from one paradigm to another cannot be understood and expressed with the help of logic. And this is indeed so, but only if we consider only one single logic (and it is precisely this that catches the eye most of all) – formal logic. However, besides it, there is another, no less important – substantive logic [56-57]. These two logics are equally important because two forms of reflection of acquired knowledge operate and interact in the human consciousness.

One of them is the substantive form, which reflects the essence of the cognized object. The essence of the object means the following:
- properties, characteristics, actions of the object;
- rules or patterns of its behaviour and interaction in time and space with other objects;
- rules or patterns of energy transformations of the object;
- possibly other aspects of its cognition.

Substantive logical thinking operates with the essence of objects and the objects themselves, based on unary and n-ary, possibly quite complex relationships between them, which were revealed in the process of cognition, including in machine learning procedures or in language models.

Another form of knowledge reflection, formalized does not delve into the essence of the cognized object, but remembers and stores the entire arsenal of knowledge about the cognized object in the form of a set of true statements (axioms) about the essence of this object, treating them as facts [58]. And subsequently it operates exclusively with these facts in accordance with its exclusively formal rules, trying to deduce consequences-inferences from the mentioned facts. The truth of axioms and the truth of the rules of inference acquire special significance in it. In this case, the cause-and-effect interdependencies between facts are reflected in the form of implicative formulas of mathematical logic, the premises of which are the previously mentioned facts conjunctively connected, and the conclusion is either one of these facts or their conjunction.

Formal logical thinking here appears in the form of a formal transformation of some initial formulas according to known rules. This is something like counting in arithmetic and algebra.
Since the period of action of formal logic completely covers the long "normal" period of development of science, it is clearly visible (obvious) to everyone, as a result of which the illusion arises that this is all logic.

There are no contradictions between the formal and substantive form of logical thinking. Simply, formal thinking is the most concise and naturally logical expression of correct meaningful thinking, thereby expressing the interconnected unity between them. Therefore, the desire for formal thinking, the focus on formal thinking are the greatest stimulus for scientific progress, the defining characteristic of human research activities. AI and LLM procedures are no exception. Finding a formal way to solve pressing problems, i.e. allowing yourself the luxury of not thinking about the method of solving a particular complex problem and carrying out a formal procedure instead of complex creative activity is the dream of any researcher in the field of formal technologies.

Not only the result of the research, but also the path leading to it, must be true at every step leading to the solution, and each step must be confirmed either by experimental data or by practice. A method is a set of rules of conduct and requirements for activity, formulated on the basis of knowledge about the properties of objective reality.

There are various types of classification of methods, which together form a methodology, which is understood both as a system of principles and methods of organizing and constructing theoretical and practical activity, and as a doctrine of this system.

We will dwell on only one, but important, division of all methods into two large groups - empirical and theoretical methods. Empirical methods do not follow from the essence of the object, and therefore contain many subjective moments. But they are such only if they do not enter as a necessary moment into the scope of the system of theoretical methods, which are built on the unity of the subject and method. Since theoretical methods act as a way for a subject to organize its activity in accordance with the essence of the subject, the empirical methods involved in the scope of the theory receive direction and objectivity within it.

Cognition begins with observation. Observation is a method of directed reflection of the characteristics of an object, allowing one to form a certain idea of the observed phenomenon. The block of observation procedures includes description, measurement, comparison.

An experiment is a more effective method, which differs from observation in that the researcher, with the help of an experiment, actively influences the object by creating artificial conditions necessary to identify previously unknown properties of the object.

To move from the substantive to the formal, they resort to modelling. The following concepts are inextricably linked with it. The modelling method is based on the creation of a model, which is a substitute for a real object due to a certain similarity with it. The main function of modelling, if we take it in the broadest sense, is to materialize, to objectify the ideal. The construction and study of a model is equivalent to the study and construction of the modelled object, with the only difference being that the latter is accomplished materially, and the former ideally, without affecting the modelled object itself. From this follows the second important function of a model in scientific knowledge - the model acts as a program of action for the forthcoming construction, building of the modelled object.

Analysis and synthesis. Empirical analysis is simply the decomposition of a whole into its constituent, simpler elementary parts. Synthesis, on the contrary, is the combination of components of a complex phenomenon.

Theoretical analysis involves identifying the main and essential in an object, which is imperceptible to empirical vision.

The analytical method includes the results of abstraction, simplification, formalization and obtaining the target result in a general form with abstract variables. Theoretical synthesis is expanding knowledge, constructing something new that goes beyond the existing basis.

Induction and deduction. Induction can be defined as a method of transition from knowledge of individual facts to knowledge of the general. Deduction is a method of transition from knowledge of general patterns to their particular manifestation. Together they form a complex method called the axiomatic method.

The integrating scientific method, which includes all the previous methods as components, is the method of cognition from the abstract to the concrete. This is a theoretical system method, consisting of such a movement of the process of cognition, which leads the researcher to a continuous, consistent and purposeful accumulation of knowledge about the studied subject, up to the reproduction of a functionally complete set of real characteristic properties of this subject.

It is precisely this method of scientific cognition that the axiomatic method.

The fundamental drawback of the substantive proof of theorems is the fact that it still remains a work of art of thinking of each researcher. This circumstance does not exclude the possibility of the presence in the proof of:

- intuitive guesses,
- analogies,
- logical ambiguities,
- logical inconsistencies,
- logical contradictions,
- and similar semantic liberties that have nothing in common with the strictness of the canons of logical thinking.

As a rule, this art in the substantive proof turns it (the proof) into an unstructured artistic work of inflated complexity, logically confusing and not always easily amenable to examination by well-disposed users. Taken together, all the listed shortcomings of substantive evidence raise doubts about each evidence until a reliable number of interpretations of this evidence by historical practice confirm its (the evidence's) impeccability. As a rule, such verification takes at least decades.

The non-standard form of the substantive proof excludes the possibility of using the formal axiomatic systems of mathematical proof of theorems known in classical mathematics, since almost always, in the substantive proof of the target theorem, there is a need to prove a number of intermediate lemmas and theorems that only a person can formulate.

Meanwhile, in formal axiomatic systems of mathematical proof of theorems, the truth of a theorem is scientifically justified as being deducible (provable) from a consistent system of premises (axioms). The conclusion or proof is a deductive chain, each step of which is justified by some logical rule belonging to formal mathematical logic.

That is why it is quite logical to accept:
as a criterion for the correctness of the substantive proof of theorems, the presence of a proof of this theorem in one of the formal axiomatic systems of mathematical proof of theorems. In order to analyze the criteria for assessing the suitability of medical equipment for use, in any of the previously mentioned countries, following the above, we will build a formal assessment model using the axiomatic method to obtain a rigorous proof of the correctness of the assessment obtained.

The purpose of mathematical modeling and the true role of such a formal mathematical proof is as follows:

- in a radical reduction in the volume of symbols in the description without losing the meaning of the phenomenon under study using formal languages of adequate mathematical structures of classical mathematics;
- in the use of ready-made algorithmic support for these adequate mathematical structures for the effective solution of problematic technological problems, i.e. problems that have pre-known solution algorithms.
- In the use of a proof-theoretical approach, instead of a model-theoretical approach, when checking the semantics of a multi-component composite formula of deductive reasoning, called a theorem, leading to a target conclusion in multi-stage reasoning when solving a given intellectual problem.

The superiority of the proof-theoretic approach over the model-theoretic approach lies in the asymptotic estimate of the complexities of these approaches. The proof-theoretic approach has a complexi-

ty estimate equal to N2, where N is the number of characters in the argument, while the model-theoretic approach has a complexity estimate equal to 2N multiplied by the Cartesian product of the cardinalities of all domains of definition for those subject variables that are included in this formula, considering the repetitions of these variables. The proof-theoretic approach uses the axiomatic method, which makes it maximally effective. Since in predicate calculus the entire structure of reasoning is built exclusively on a priori true components of reasoning, including the conclusion in the reasoning, then mathematical proof only establishes the truth or falsity of a composite formula called a theorem.

To evaluate the entire spectrum of knowledge about dependent processes, theoretical science is indispensable. This knowledge must initially be obtained and formed by theoretical sciences into a structure accessible to universal formal procedures and simple for formal use. Axiomatic modelling allows this to be done in a format of minimal volume and minimization of experimental tests.

7. Rationale for Improving Certification Processes

Despite the common goal of ensuring product safety and efficacy, current medical device certification processes in the UK, EU and Ukraine are accompanied by significant administrative and technical barriers. These barriers include long certification periods, high costs of preparing technical documentation and heterogeneity of requirements between different markets.

The need to optimize processes is due to the following factors:
Reduction of timeframes and costs. Duplication of certification procedures for different markets (UKCA, CE and national Ukrainian certificates) leads to a significant extension of product approval periods and an increase in manufacturers' cost. Optimization and unification of technical documentation, as well as the introduction of digital control systems (e.g. integration with the EUDAMED database), will reduce operating costs and speed up the certification process.

Harmonization of regulatory requirements. Despite the common focus on ensuring safety, the differences between the regulatory systems of the UK, EU and Ukraine create difficulties for manufacturers operating in the international market. Simplification and harmonization of requirements will reduce the number of repetitive inspections, which is especially important for small and medium-sized enterprises experiencing financial and resource constraints.

Increasing transparency and control efficiency. The integration of international standards such as ISO 13485 and ISO 14971 into certification processes will create a more predictable and transparent conformity assessment system, where risk assessment, clinical safety and product efficacy will be key aspects. This, in turn, will increase patient and physician confidence in new products, and will also strengthen the reputation of manufacturers in the global market.

Facilitating innovation and global cooperation. Simplifying regulatory requirements will create favorable conditions for the rapid implementation of innovative medical technologies, allowing manufacturers to more quickly adapt to new requirements and enter international markets without significant delays. International cooperation, for example through the International Medical Device Regulators Forum (IMDRF), promotes the exchange of experience and harmonization of approaches, which will have a positive impact on the global competitiveness of the industry.

Improving and standardizing certification processes for medical devices will not only reduce the administrative burden and costs for manufacturers, but will also ensure a higher level of product safety and quality, which is key to protecting public health worldwide.

8. Conclusion

Based on the comparative analysis of medical device certification processes in the UK, the EU and Ukraine, the following conclusions can be drawn. All three regulatory systems aim to ensure a high level of safety and efficacy of medical products, which is a fundamental condition for protecting public health. However, differences in regulations, conformity assessment methods and post-marketing control procedures create significant challenges for manufacturers seeking to enter the international market.

In the UK, the system demonstrates some flexibility for low-risk products due to the possibility of self-assessment, but at the same time faces additional difficulties associated with the need to obtain both UKCA marking and CE conformity assessment in the context of post-Brexit regulation [22, 24]. The EU, with its uniform and strict MDR regulation, ensures a high level of safety through complex conformity assessment procedures, but such requirements lead to significant costs of time and resources, which especially affects small and medium-sized enterprises [28, 29]. Ukraine, adapting its system to European standards, faces local administrative and language barriers, as well as variations in the work of national conformity assessment bodies, which can lead to delays and increased costs [30, 32, 33].

Based on these observations, optimization and unification of certification processes seem necessary to reduce time and financial costs, reduce duplication of procedures and ensure faster and more predictable entry into international markets. Harmonization of regulatory requirements, as well as the introduction of digital tools (e.g. integration with EUDAMED) contribute to the creation of a more transparent and effective control system, which will ultimately increase the competitiveness of manufacturers and improve patient access to innovative medical technologies [53, 54, 59].

Thus, further improvement of regulatory processes requires close international cooperation, exchange of experience and ongoing dialogue between regulators, which will allow adapting the certification system to the dynamically developing market of medical devices and ensure a high level of safety at the global level.

As for the solution of the problem of assessing a particular medical equipment using the axiomatic method, the appropriateness of the proposed approach to assessing the suitability of equipment is dictated by the requirements of transparency, objectivity and dynamism of the medical equipment market in modern medicine. High technologies, the expansion of artificial intelligence and the inevitability of dynamic changes in views on the devices used in medicine associated with the rapid improvement of technologies require new approaches to assessment. A single formal procedure, initially modeled for the purpose of its mobility to improve the requirements for assessment, is exactly the result that is required for an automatic procedure for checking devices for suitability for use in the medical field.

The advantages of the proposed axiomatic method are that it allows you to combine in one problem both data from completely different areas, and problems and the results of their solution that do not intersect in any way, constituting formal reasoning.

A formal approach to solving practical problems has advantages that transform practical problems into formal ones, for the implementation of a single approach to solving any problems. This procedure is simple and reasonably attractive due to its objectivity and universality. It is also necessary to consider the responsibility and increased requirements for the truth of formal procedures. Any doubts about the correctness and universality of each formal step, as a threat of losing truth as a result of applying formal procedures, require the elimination of this threat in the very basis of formal methods. Otherwise, the damage from the slightest error will have catastrophic cumulative consequences. Scrupulousness and meticulousness in the creation of formal methods, extraordinary attention to the formation of the basis of formal theories, according to the authors, are today the key to solving the problem of threats to AI security and the path to a restart (new opportunities in formal sciences and AI sciences).

Authors' Contributions

Conceptualisation and methodology, Viktoria Kondratenko; validation, Leonid Slovianov; formal analysis, Viktoria Kondratenko; data curation, Leonid Slovianov; writing—original draft preparation, Viktoria Kondratenko; writing—review and editing, Leonid Slovianov; All authors have read and agreed to the published version of the manuscript.

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