JEL Classification: L15

UDC 005:614(076)

DOI: 10.30857/2415-3206.2026.1.4

MAIN ORGANIZATIONAL AND ECONOMIC VECTORS OF IMPLEMENTATION OF CERTIFICATION SYSTEMS FOR MEDICAL DEVICE MANAGEMENT

Roman MYKHALKO
Kyiv National University of Technologies and Design, Ukraine

INTRODUCTION. Implementation of certification systems for quality management (QMS) for medical devices in Ukraine, in particular the ISO 13485 standard (in Ukraine it is valid as DSTU EN ISO 13485:2018), is a critically important requirement for manufacturers, importers and distributors who seek to work in accordance with technical regulations and European standards. This standard is harmonized with EU requirements and provides a presumption of conformity with the technical regulations of Ukraine.

THE PURPOSE OF THE STUDY is to substantiate the main organizational and economic vectors of implementation of certification systems for medical device management.

THE HYPOTHESIS OF THE STUDY is to investigate the organizational and economic vectors of implementation of certification systems for medical device management.

RESEARCH METHODS: generalization, deduction, induction, analysis and synthesis, abstraction.

CONCLUSIONS. Accession to the European Union opens up new political and economic opportunities for the country and contributes to improving the quality of life of every Ukrainian. The implementation of European standards and best practices will ensure modern medicine, transparent conditions for business and reliable protection of citizens' rights. Analysis of the institutional framework revealed that Ukraine has a multi-level regulatory model, within which the ISO 13485 standard, through a mechanism, actually acquires the status of mandatory for manufacturers. The transition of the Ukrainian medical industry to more stringent requirements, similar to the EU Regulations (MDR/IVDR), is justified, which is due to the strategic course towards European integration and the opening of access to the European Union market.

KEYWORDS: harmonization of national legislation with European standards; European standards; implementation of certification systems for medical device management; quality management systems.

NUMBER OF REFERENCES	NUMBER OF FIGURES	NUMBER OF TABLES
12	0	0

Received: 21.04.2026	Revised: 11.05.2026	Accepted: 29.05.2026	Published: 01.06.2026

JEL Classification: L15

УДК 005:614(076)

DOI: 10.30857/2415-3206.2026.1.4

ОСНОВНІ ОРГАНІЗАЦІЙНО-ЕКОНОМІЧНІ ВЕКТОРИ ІМПЛЕМЕНТАЦІЇ СЕРТИФІКАЦІЙНИХ СИСТЕМ МЕНЕДЖМЕНТУ МЕДИЧНИХ ВИРОБІВ

Роман МИХАЛКО
Київський національний університет технологій та дизайну, Україна

ВСТУП. Імплементація сертифікаційних систем менеджменту якості (СУЯ) медичних виробів в Україні, зокрема стандарту ISO 13485 (в Україні діє як ДСТУ EN ISO 13485:2018), є критично важливою вимогою для виробників, імпортерів та дистриб'юторів, що прагнуть працювати згідно з технічними регламентами та європейськими стандартами. Цей стандарт гармонізований із вимогами ЄС і забезпечує презумпцію відповідності технічним регламентам України.

МЕТА ДОСЛІДЖЕННЯ: обґрунтувати основні організаційно-економічні вектори імплементації сертифікаційних систем менеджменту медичних виробів

ГІПОТЕЗА ДОСЛІДЖЕННЯ: дослідити організаційно-економічні вектори імплементації сертифікаційних систем менеджменту медичних виробів

МЕТОДИ ДОСЛІДЖЕННЯ: узагальнення, дедукції, індукції, аналізу і синтезу, абстрагування.

ВИСНОВКИ. Вступ до Європейського Союзу відкриває нові політичні та економічні можливості для країни та сприяє підвищенню якості життя кожного українця. Впровадження європейських стандартів і найкращих практик забезпечить сучасну медицину, прозорі умови для бізнесу та надійний захист прав громадян. Аналіз інституційної бази виявив, що в Україні діє багаторівнева регуляторна модель, у рамках якої стандарт ISO 13485 через механізм фактично набуває статусу обов’язкового для виробників. Обґрунтовано перехsl української медичної промисловості до більш жорстких вимог, подібних до Регламентів ЄС (MDR/IVDR), що зумовлено стратегічним курсом на євроінтеграцію та відкриттям доступу до ринку Європейського союзу.

КЛЮЧОВІ СЛОВА: гармонізації національного законодавства з європейськими стандартами; європейські стандарти; імплементація сертифікаційних систем менеджменту медичних виробів; системи менеджменту якості.

Task statement. Implementation of certification systems for medical device management (e.g. ISO 13485) in Ukraine is based on harmonization of national legislation with European standards (EU MDR/IVDR) and introduction of risk-based approaches. This involves a comprehensive transformation of organizational processes and economic justification of investments in quality.

The main organizational and economic vectors include:

1. Organizational vectors (management and process):

• Integration of the quality management system (QMS): Implementation of DSTU ISO 13485 standards, which ensures compliance of medical devices with established safety and functional requirements at all stages of the life cycle.

• Risk-based approach: Risk management for patient safety and product effectiveness, which becomes a critical element of certification.

• Adaptation to healthcare reforms: Interaction of medical institutions and manufacturers with new regulatory requirements, development of leadership and personnel competencies.

• Recognition and certification procedures: Organization of processes for recognizing European certificates (EC) in Ukraine, which simplifies market access and ensures compliance with technical regulations.

2. Economic vectors (financial and market):

• Economic efficiency of quality: Minimization of losses from defects and non-conformities through the functioning of the quality system, which increases the competitiveness of products.

• Investments in certification: Costs for development, implementation, training of personnel and services of notified bodies for conformity assessment.

• Access to markets: Obtaining a certificate of conformity as a mandatory condition for access to the Ukrainian and EU medical device market.

• Crisis management: Formation of sustainable management models capable of adapting to changes, which is important for the pharmaceutical and medical business.

The implementation of these vectors ensures the safety of medical devices and increases the overall economic efficiency of the functioning of medical device enterprises.

The purpose of the study is to substantiate the main organizational and economic vectors of implementation of certification systems for medical device management.

Presentation of the main material

Key aspects of ISO 13485 implementation in Ukraine:

1. Current version and harmonization: Ukraine has DSTU EN ISO 13485:2018, which is identical to the international standard ISO 13485:2016.

2. For whom is it mandatory:

- Manufacturers: Implementation of a QMS is mandatory for Ukrainian manufacturers engaged in the design, development, production, installation and maintenance of medical devices.

- Importers/Distributors: Although certification is often voluntary for them, having an ISO 13485 certificate significantly simplifies conformity assessment procedures and increases trust.

3. Relationship with Technical Regulations: Implementation of ISO 13485 helps to fulfill the requirements of the Technical Regulations:

• No. 753 (medical devices),

• No. 754 (in vitro diagnostics),

• No. 755 (active medical devices).

Stages of system implementation (QMS)

The implementation usually goes through the following steps:

• Diagnostic audit (pre-audit): Analysis of current business processes and documents for compliance with the requirements of the standard.

• Documentation development: Creation of a Quality Manual, standard operating procedures (SOPs), instructions and logs.

• Personnel training: Training employees to work according to new procedures.

• Implementation: Implementation of QMS requirements in production/in the company.

• Internal audit: System verification before certification.

Certification procedure:

1. Selection of a certification body: The body must be accredited (for example, an accredited body such as IMPROVE MEDICAL or USA).

2. Submission of application and documents.

3. Certification audit (two stages):

- Stage 1: Analysis of documentation (preliminary assessment).

- Stage 2: On-site audit (inspection of production areas).

4. Obtaining a certificate: Issuance of a certificate of conformity to ISO 13485 (usually valid for 3 years).

Benefits of implementation:

• Market access: Possibility of free circulation of medical devices in Ukraine and simplified access to EU markets.

• Risk management: Minimization of risks for patients and users.

• Quality control: Ensuring stable product quality and process efficiency.

In Ukraine, the implementation of quality management systems (QMS) for medical devices, in particular according to the ISO 13485 standard, is not only a tool for competitiveness, but also a legislative requirement for the legal sale of products.

Key aspects of implementation in Ukraine in 2026:

1. Legislative obligation:

• The presence of an implemented QMS is mandatory for all classes of medical devices in accordance with the Technical Regulations (CMU Resolutions No. 753, No. 754, No. 755).

• Compliance with the national standard DSTU EN ISO 13485:2018 provides a "presumption of conformity" with the requirements of the technical regulations.

2. Harmonization with the EU (MDR/IVDR):

• During 2025–2026, Ukraine will gradually transition to new rules harmonized with the European regulations MDR (EU 2017/745) and IVDR (EU 2017/746).

• This involves strengthening the requirements for technical documentation, digital product registration and the implementation of the UDI system (unique product identification).

3. Implementation and certification process:

• Documentation development: Creation of risk management procedures (ISO 14971), product traceability, personnel management and infrastructure.

• Audit: Conducted by accredited conformity assessment bodies (e.g. Ukrmetrteststandart, Improve Medical and others), which have a certificate from the National Accreditation Agency of Ukraine (NAAU).

• Support: The organization must keep quality records throughout the product life cycle, but not less than 2 years from the date of release.

Key business benefits:

• Access to international markets: The international ISO 13485 certificate facilitates exports to the EU and other countries.

• Participation in procurement: The presence of a certificate is critical for participation in government tenders and reimbursement programs.

• Quality control: Reduction of the number of defects through clear identification and monitoring at all stages of production.

Research conclusions and prospects. Harmonization of Ukrainian legislation on medical devices with EU regulations (MDR 2017/745 and IVDR 2017/746) is a key stage of Ukraine's European integration in the healthcare sector, planned for 2025–2026. This process involves the transition from outdated directives (MDD) to stricter European safety and quality standards.

Main changes and requirements within the framework of harmonization (2025–2026):

• Strengthening requirements for technical documentation: Manufacturers and importers must update technical files (Technical File), ensuring their compliance with the requirements of Annexes II and III of the MDR/IVDR. This includes detailed data on clinical evaluation, test results and risk management.

• Digital product registration: The creation of a national electronic register of medical devices is being implemented, which is interconnected with the European EUDAMED database. Products must be registered in this register before being placed on the market.

• UDI (Unique Device Identification): The implementation of a UDI is mandatory to improve product traceability. It is expected that UDI (GS1 DataMatrix barcode) marking will become mandatory for high-risk products (IVDR classes C, D and MDR III/IIb).

• Updated classification: Many products, especially in vitro diagnostics, will move to higher risk classes (e.g. from A to B/C/D), which will require the mandatory involvement of Notified Bodies (NBs).

• New requirements for post-marketing surveillance (PMS): Manufacturers are required to implement stricter monitoring systems for products after they are on the market.

Recommendations for business:

1. Update documentation: Start updating technical documentation to MDR/IVDR standards now.

2. Ensure UDI: Adapt labeling and packaging to UDI requirements.

3. Check classification: Make sure that the product classification is correct according to the new rules.

These changes are aimed at increasing the efficiency of conformity assessment procedures and harmonizing the Ukrainian market with the European one, which will ensure better access of patients to quality medical devices.

REFERENCES:

DSTU EN ISO 13485:2018 Medychni vyroby. Systema upravlinnia yakistiu. Vymohy do rehuliuvannia [Medical devices – Quality management system – Regulatory requirements] (EN ISO 13485:2016, IDT; ISO 13485:2016, IDT). URL: https://icr-cert.com.ua/iso-13485-2016-medical-devices-qualitymanagement-systems-qms-md/ [in Ukrainian].

DSTU EN ISO 14971:2022 Vyroby medychni. Nastanovy shchodo upravlinnia ryzykom shchodo medychnykh vyrobiv [Medical devices. Guidance on risk management for medical devices] (EN ISO 14971:2019, IDT; ISO 14971:2019, IDT). URL: https://www.iso.org/obp/ui/ru/#iso:std:iso:14971:ed-3:v1:en [in Ukrainian].

DSTU EN ISO/IEC 17000:2021 Otsiniuvannia vidpovidnosti. Slovnyk terminiv i zahalni pryntsypy [Conformity assessment. Glossary of terms and general principles] (EN ISO/IEC 17000:2020, IDT; ISO/IEC 17000:2020, IDT). URL: https://zakon.isu.net.ua/sites/default/files/normdocs/dstu_en_iso_iec_17000_2021_ocinyuvannya_vidpo vidnosti._slovni.pdf [in Ukrainian].

DSTU ISO 9000:2015 Systemy upravlinnia yakistiu. Osnovni polozhennia ta slovnyk terminiv [Quality management systems. Basic provisions and glossary of terms] (ISO 9000:2015, IDT). URL: https://zakon.isu.net.ua/sites/default/files/no rmdocs/dstu_iso_9000_2015.pdf [in Ukrainian].

DSTU ISO 9001:2015 Systemy upravlinnia yakistiu. Vymohy [Quality management systems. Requirements] (ISO 9001:2015, IDT). URL: https://khoda.gov.ua/image/catalog/files/%209001.pdf [in Ukrainian].

Dubinskyi, S. V. (2016). Problemy zabezpechennia yakosti posluh v medychnii haluzi Ukrainy [Problems of ensuring the quality of services in the medical industry of Ukraine]. *Yevropeiskyi vektor ekonomichnoho rozvytku*, 1 (20), 51–59 [in Ukrainian].

Ivashkiv, Yu. D., Miedviedieva, N. A., & Muzyka, V. P. (2018). Rozroblennia elementiv systemy upravlinnia yakistiu v umovakh medychnoi ustanovy [Development of elements of a quality management system in a medical institution]. *Standartyzatsiia. Sertyfikatsiia. Yakist*, (2018) [in Ukrainian].

Linhur, L., Martyniuk, O., & Yesina, O. (2023). Vprovadzhennia standartiv yakosti v upravlinnia pidpryiemstvamy maloho ta serednoho biznesu [Implementation of quality standards in the management of small and medium-sized businesses]. *Naukovyi visnyk Poltavskoho universytetu ekonomiky i torhivli. Seriia "Ekonomichni nauky"*, 1 (107), 12–18. DOI: https://doi.org/10.37734/2409-6873-2023-1-2 [in Ukrainian].

Martyniuk, O. A., & Kurdybanska, N. F. (2016). Vprovadzhennia systemy upravlinnia yakistiu v medychnykh zakladakh [Implementation of a quality management system in medical institutions]. *Prychornomorski ekonomichni studii*, (6), 80–84. URL: http://bses.in.ua/journals/2016/6-2016/18.pdf [in Ukrainian].

Patiota, L. E., Kharchenko, T. F., Levytska, V. M., Kharchenko, O. A., Yurchenko, T. V., & Denysenko, H. O. (2014). Cuchasni vymohy do sertyfikatsii medychnykh vyrobiv [Modern requirements for certification of medical devices]. *Suchasni problemy toksykolohii, kharchovoi ta khimichnoi bezpeky*, (1–2), 80–83. URL: http://nbuv.gov.ua/UJRN/spt_2014_1-2_11 [in Ukrainian].

Pro akredytatsiiu orhaniv z otsinky vidpovidnosti [On accreditation of conformity assessment bodies: Law of Ukraine dated 17.05.2001 No. 2407-III]. URL: https://zakon.rada.gov.ua/laws/show/2407-14#Text [in Ukrainian].

Pro zatverdzhennia pereliku natsionalnykh standartiv, vidpovidnist yakym nadaie prezumptsiiu vidpovidnosti medychnykh vyrobiv vymoham Tekhnichnoho rehlamentu shchodo medychnykh vyrobiv [On approval of the list of national standards, compliance with which provides a presumption of

conformity of medical devices with the requirements of the Technical Regulations on Medical Devices: Order of the Ministry of Health of Ukraine dated 11.10.2017 No. 1245]. URL: https://zakon.rada.gov.ua/rada/show/v1245282-17#Text [in Ukrainian].

AUTHOR (S) BIOSKETCHES

Mykhalko Roman, PhD Student, Kyiv National University of Technologies and Design, Ukraine.

https://orcid.org/0009-0001-1801-6305
E-mail: r.mykhalko@gmail.com

HOW TO CITE THIS ARTICLE
Mykhalko, R. (2026). Main organizational and economic vectors of implementation of certification systems for medical device management. *Management*, 1(43): 40–47. https://doi.org/10.30857/2415-3206.2026.1.4.