

STATEMENT ON THE POLICY OF QUALITY AND INFORMATION SECURITY

The Institute for Medicines and Medical Devices (CInMED) was established as a professional and scientific institution with the aim of implementing regulations in the field of medicines and medical devices.

The mission of the Institute is to ensure the quality, safety, and efficacy of medicines and medical devices with appropriate performance.

The vision of the Institute is a systematically and regulatory well-organized area of medicines and medical devices.

The established Policy of the Integrated Quality and Information Security Management System is based on modern principles aimed at meeting the needs, requirements, and expectations of patients and users in the following areas:

- issuing marketing authorisations for medicines,
- issuing import-export authorisations for medicines and issuing certificates and opinions,
- issuing import-export and transit authorisations for controlled substances,
- registration of medical devices,
- approval of clinical trials for medicines in human and veterinary medicine,
- monitoring adverse reactions of medicines and medical devices through the vigilance system,
- monitoring consumption and determining maximum prices of medicines,
- inspection of manufacturing, wholesale distribution, pharmacovigilance and clinical trials of medicines, and supervision of GxP compliance, and
- monitoring and detection of substandard and falsified medicines.

The achievement of the objectives of this Policy is ensured through the implementation and maintenance of an integrated quality and information security management system in accordance with the requirements of ISO 9001:2015 and ISO/IEC 27001:2022 standards, through the application of the following principles:

- continuous improvement of the quality and efficiency of work processes in line with Good Regulatory Practice,
- implementation of continuous training of employees in professional and scientific fields,
- risk management to ensure goal achievement, business continuity, and information security,
- consistent monitoring and application of national and EU regulations in the field of medicines and medical devices,
- improvement of the integrated quality and information security management system in cooperation with users, suppliers, and external experts, through a high level of ethical and professional collaboration,
- professional and impartial conduct in the execution of business activities,
- maintaining a high level of information security, including confidentiality, integrity, and availability,
- monitoring and implementation of technological innovations.

Our obligation is to actively work at all levels and in our workplaces on promoting, developing, and improving the quality system and the values of the Institute, which entails the continuous:

- monitoring of all process performance,
- increasing of competencies, efficiency, and work effectiveness,
- review of the risk treatment plan, and
- review and evaluation of the effectiveness of the quality system.

In the area of information security, this policy aims to facilitate business improvement through the adoption of secure business practices and management systems, reduce potential damage and costs, improve the

Institute's image, increase efficiency, and support compliance with data protection regulations. The policy applies to:

- employees of the Institute, interns and volunteers,
- external experts, outsource partners, consultants and third parties collaborating with the Institute,
- systems, applications, and infrastructure used for data processing and information management,
- information in all formats – paper, electronic, verbal, etc.,
- information owned by the Institute as well as information received from clients and interested parties,
- facilities and premises where information is accessed and stored.


This policy sets out the direction and commitment of the Institute to the maintaining and improving of the information security system, in line with the requirements of relevant laws, regulations, and standards. The objectives stemming from this policy, with regard to information security, include:

- reducing risks to information security,
- ensuring proper handling of information in accordance with business needs and applicable laws,
- developing awareness of the importance of information security,
- maintaining documented records as evidence of implemented activities,
- continuous improvement of the system, based on audits, feedback and performance analysis.

Information, regardless of its form, holds value and must be appropriately protected. Information security covers people, processes, services, hardware, software and infrastructure, and is part of the Institute's overall management system. In order to protect the system from threats such as: cyberattacks, viruses, unauthorized access, improper transmission, unauthorized disclosure of information, misuse of personal data, natural disasters, compromised physical security or technical malfunctions – the Institute adopts this policy as the basis for implementing all information security measures.

In achieving the stated objectives, I expect the support and full commitment of all employees.

Podgorica, 7 July 2025


Managing Director

Snežana Mugoša, MD, MSc, PhD, spec.