

# Quality Policy of CC Diagnostics

The whole team of CC Diagnostics, led by the Management Team, is committed to producing safe and effective in vitro diagnostic devices and research materials, and reagents that not only meet regulatory requirements and related standards but also surpass customer needs to reduce insecurity concerning the onco-gynaecologic situation of women. We foster a culture of continuous improvement, emphasizing risk management as a core element of our process. The team is committed to maintaining an effective quality management system that consistently complies with all applicable requirements by continually pursuing and reviewing measurable objectives that align with this policy and the company's strategic direction.

We are committed to aligning our Quality Management System with the Organization for Economic Cooperation and Development (OECD) principles to ensure transparency, integrity, and accountability in all aspects of our product lifecycle. This alignment underpins our dedication to delivering safe, effective, and reliable medical devices that comply with international standards.

## **1. Quality and Integrity**

We ensure that all processes, from design and development to testing and manufacturing, adhere to high standards of quality and scientific integrity. This includes rigorous documentation, robust testing, and validation processes to maintain product consistency, safety, and performance.

## **2. Transparency and Accountability**

Our company fosters a transparent approach to product quality management. Clear documentation and traceable records are maintained at every stage, allowing stakeholders—including regulatory bodies, customers, and partners—to assess compliance with quality standards. Accountability is a core element, with defined roles and responsibilities across our team to uphold the QMS.

## **3. Data Governance and Confidentiality**

We adhere to best practices in data governance, ensuring that all data related to product development, clinical testing, and manufacturing processes are accurate, secure, and confidential. Customer data is also handled with utmost discretion. Data integrity is fundamental, with controls in place to protect against unauthorized access or data manipulation.

## **4. Continuous Improvement and Risk Management**

Guided by OECD principles, we strive for continuous improvement in all areas of our QMS. This includes routine evaluations and the implementation of corrective actions to address any identified risks or areas of non-compliance. Risk management is embedded in our processes, ensuring proactive identification and mitigation of risks that could impact product quality and patient safety.

## **5. Ethical Responsibility and Regulatory Compliance**

We uphold ethical standards in all aspects of our operations, aligning with both OECD principles and regulatory requirements for medical devices. This involves conducting all activities in compliance with applicable health, safety, and environmental regulations to promote patient well-being and public health.

## **6. Business ethics**

We uphold responsible business conduct by complying with applicable laws and international standards, maintaining a zero-tolerance approach to corruption, and ensuring transparency and traceability across our operations and supply chain. We foster a culture of integrity through continuous training, leadership accountability, and open communication, and we engage stakeholders responsibly by respecting human rights, promoting fair competition, and contributing positively to the communities we serve.

By embedding OECD principles in our Quality Policy, we reinforce our commitment to producing medical devices that meet the highest standards of quality, safety, and ethical responsibility, supporting our mission to make a positive impact in healthcare. Whenever a supplier of our materials is evaluated, their own quality policy shall be assessed against these principles as well.

Generally, CC Diagnostics has defined several high-level quality objectives:

1. We develop products that aid in cancer diagnostics according to the latest scientific findings.
2. For our customers, we aim to solve both requests and complaints as quickly as possible.
3. We increase our productivity by working with well-controlled partners
4. Our employees will be optimally prepared for their tasks by receiving comprehensive training in this quality management system.
5. We gain the trust of our customers through honesty and transparency.