

Author	Dr. med. Stefan Preis	Document No	A.5.0.0
Approved	03/01/2023	Valid until	01/10/2023
Approved by	Stefan Preis	Version	6.0



A.5 Quality and Security Management Policy

The management of Clinovate NET GmbH & Co KG, officially declares its involvement in the QMS and ISMS systems with this policy aimed to:

Continuous assurance of the quality of the provided services and the security of the information related to the development and maintenance of the software.

To implement this policy, the management of Clinovate NET directs its efforts in the following area:

The success of our company depends on its ability to meet the requirements and expectations of our customers, staff and owners and our efforts are focused on efficient management of processes affecting the quality and security of information as a prerequisite for achieving significant profitability and ultimate economic prosperity.

We unconditionally comply with the requirements for continuous improvement of IMS, based on risk analysis, which serves as a preventive tool to meet the needs of stakeholders. We develop our softwares in a secured process of Computer System Validation CSV and we use the CAPA method in order to prevent incidences.

We affirm the primary role of the law and guarantee its observance.

Our main goal is to help our customers collect CLINICAL DATA, by developing INNOVATIVE SOFTWARE solutions, that are SAFE and EASY to use, while we meet customer requirements and follow the requirements of **ISO 9001:2015, ISO/IEC 27001:2017, ICH GCP, FDA: 21 CFR part 11 and GDPR**, in connection with which the top management of the company has defined and documented its quality and information security policy, which is the basis for setting our goals and commitments.

In our effort to achieve the main goal, we set yearly goals, that are steps in the pointed direction. The goals are defined in a document **ISMS Goals YYYY**. There we also define our KPIs to measure the results

To achieve these goals we commit ourselves by providing human resources for all processes as described in **ISMS Description of processes and responsible individuals**, all technical resources as described in **ISMS Asset register** and all necessary financial and time resources that are evaluated at least once per year.

We use the most competitive and innovative solutions in our work.

Our strategic focus is to increase the competitiveness of the organization by continuously improving customer service and optimizing deadlines for our activities, developing the strengths of the organization, expanding the range of products offered and maintaining mutually beneficial relationships with our suppliers.

We provide the framework for setting and reviewing information quality and security objectives.

By maintaining constant contact with customers we immediately clarify their needs and meet their requirements by receiving feedback:

Reviewed	03/12/2022	Document type	CONTROLS
Reviewed by	Petko Iliev		



Author	Dr. med. Stefan Preis	Document No	A.5.0.0
Approved	03/01/2023	Valid until	01/10/2023
Approved by	Stefan Preis	Version	6.0



- ensuring the CONFIDENTIALITY of the information by applying a system of approved rules for working with it.
- ensuring the INTEGRITY of the information - ie. its accuracy and fidelity.
- ensuring AVAILABILITY of information by providing reliable and timely access to it.

We provide periodic updating of the organization's policy to be adequate to the strategic direction of the company, documentation, implementation and maintenance.

We provide continuous process for maintaining and effective use of available resources, improving the qualification, initiative and motivation of staff through training for better functioning of the organization and for fuller satisfaction of customer requirements.

The CEO of Clinovate NET supports other management roles to prove their leadership in their areas of responsibility.

The CEO of Clinovate NET is committed to constantly improve and maintain the efficiency of the quality and information security management system, in accordance with the international standard **ISO 9001:2015** and **ISO/IEC 27001: 2017**.

As a CEO of CLINOVATE NET GmbH & CO KG, I DECLARE MY PERSONAL PARTICIPATION AND RESPONSIBILITY FOR IMPLEMENTATION OF THE ANNOUNCED POLICY, ENSURING THE PROSPERITY OF THE ORGANIZATION.

CEO: Dr. med Stefan Preis

Reviewed	03/12/2022	Document type	CONTROLS
Reviewed by	Petko Iliev		

