"AURIGA"

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Quality Manual

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About «Auriga»

«Auriga» has been providing services related to the development high-technology software to customers from Russia, the USA, and Europe for more than 25 years. The company's headquarters is located in the USA, and its development centers are located in Russia and Lithuania. The company provides services covering the full range of software product development, including mobile software, embedded software, complex corporate applications, and web applications.

Founded in 1990, «Auriga» became one of the first Russian customized software development companies. The company provides services related to allocated engineering team management and executes software development projects for high-tech customers and software developers, allowing them to launch new projects, easily scale the size of a team to the needs of the project, and focus on meeting strategic business goals.

«Auriga» offers a wide range of services related to new software product development, support and maintenance, testing, verification, and validation. The company specializes in software development for banks, document circulation systems, embedded systems, mobile devices, cloud technologies, processing and streaming of multimedia content, and high-technology medical equipment.

«Auriga» pays great attention to communication, team management issues, and the engineering culture of its employees, and it aims at building long-term relationships with its customers. This results in real transparency, honest evaluations, and the absence of unpleasant surprises for customers. The company's customers include, among others, IBM, Draeger Medical, CROC, Yandex, and Volgo-Vyatsky Bank of Sberbank RF. Some of them have been partners of «Auriga» for more than 20 years.

1. Scope

The quality management system (QMS) of «Auriga» is applicable to the activity of «Auriga» in the sphere of the provision of services related to software (SW) testing for medical devices (MD). SW testing services are provided to customers, who are developers of SW for MD, at any stage of the SW development lifecycle in which they are required.

SW testing services include the design and execution of manual and automated tests. The service provided related to manual and automated test design is described in Section 7.3 of the present Quality Manual. The service provided related to manual and automated test execution is described in Section 7.5 of the present Quality Manual. The planning of the work related to providing SW testing services is organized in two steps: the preliminary collection and analysis of requirements before signing the contract (presale), as described in Section 7.2, and the planning of the SW testing service lifecycle for MD, as described in Sections 7.1, 7.2, 7.3, and 7.5.

The result of the service provided is presented in the reports on the executed work. The service result is unique (not part of a series) and does not imply activities of installation, packaging, storage in the process of delivery, delivery, sterilization, or product purity assurance.

The provided services of «Auriga» are not subject to regulatory requirements in the sphere of work with MD, as the company does not produce MD but performs SW testing for MD. Therefore, none of the requirements to QMS connected with legislative acts in the sphere of MD is applicable to the provided services. For the same reason, the use of explanatory notices is not applicable to the activity of «Auriga».

«Auriga» does not conduct calibration or checking of monitoring and measurement equipment. Rather, it has companies that have the appropriate accreditation certificates perform these tasks.

2. Normative References

The QMS of «Auriga» uses the normative references to standards:

- ISO 13485:2016 «Medical Devices. Quality Management Systems. Requirements for Regulatory Purposes»;
- ISO 14971:2007 «Medical Devices. Application of Risk Management to Medical Devices»;
- ISO 9000:2015 «Quality Management Systems. Fundamentals and Vocabulary»;
- ISO 19011:2011 «Guidelines for Auditing Management Systems»;
- ISO/IEC 17025:2005 «General Requirements for Competence of Testing and Calibration Laboratories».

3. Terms and Definitions

Name	Definition
QMS	Quality Management System
QMS Process Diagram	Set of documents describing and determining the interrelation of processes: •«SQ-71 Product Life Cycle» •«SQ-8 QMS Self-regulation Cycle» •«SQ Service Processes»
SW	Software
MD	Medical Device

4. Quality Management System

4.1. General Requirements

4.1.1 «Auriga» documents its QMS and maintains its efficiency in accordance with the requirements of the present standard and the applied regulatory requirements. «Auriga» establishes, implements, and maintains the requirements, procedures, activities, or events that should be documented in accordance with the requirements of the present Quality Manual.

4.1.2 «Auriga» defines the processes necessary for the QMS and their implementation within the organization and offers an account of the roles taken.

«Auriga» adopts the risk-oriented approach to the management of the processes necessary for QMS.

«Auriga» determines the sequence and interaction of these processes. The information on the processes is located in the «QMS Process Diagram».

4.1.3 «Auriga» specifies the criteria and methods necessary to ensure efficiency in the implementation and management of each process in the QMS, as described in «SQ-84 Data Analysis».

«Auriga» ensures the availability of the resources and information necessary for the support of these processes and their monitoring.

«Auriga» performs the actions necessary to achieve the planned results and to maintain the efficiency of these processes.

«Auriga» performs monitoring and measurement in accordance with the QMS procedures and «SQ-84 Data Analysis».

«Auriga» specifies and maintains the records in usable conditions to demonstrate compliance with the requirements of the present standard as described in the procedures and in «SQ-425 Record Management».

4.1.4 «Auriga» performs QMS process management in accordance with the requirements of the present Quality Manual.

Changes made to these processes are evaluated by «Auriga» from the perspective of their influence on the QMS and from the perspective of their influence on MD produced within the framework of the QMS.

Changes made to these processes are controlled by «Auriga» in accordance with the requirements of the present Quality Manual.

Making changes to the process is described in the standard «SQ-424 Document Management».

4.1.5 «Auriga» delegates to external suppliers the task of the checking and calibration of equipment, influencing the product conformity to requirements. Monitoring and management of the checking and calibration process is impossible due to the specific nature of the activity.

4.1.6 «Auriga» documents the usage validation process of SW used in the QMS in the standard «SQ-416 Software Usage Validation». Applications of this SW are validated before usage and, if feasible, after making changes to the SW or its usage. Validation and revalidation activity of SW is proportional to the risk connected with the usage of this SW.

«Auriga» maintains in usable conditions the records on validation in accordance with «SQ-416 Software Usage Validation».

4.2. Documentation Requirements

4.2.1. General

«Auriga» includes in its QMS the following documents:

- quality policy;
- quality objectives;
- Quality Manual;
- documented standards, procedures, and records required by the present Quality Manual;
- documents, including the records, specified by «Auriga» as necessary to ensure efficient planning and execution of processes and their management;
- other applicable documentation to ensure the quality of provided services (e.g., international standards).

4.2.2. Quality Manual

«Auriga» develops and maintains in usable conditions the «Quality Manual». The Quality Manual determines the QMS processes and QMS documentation structure in the «QMS Process Diagram».

4.2.3. Medical Device File

For each project connected with an MD, «Auriga» creates and maintains in usable conditions a «Medical Device Testing Project File». It contains documents (in accordance with standards

«SQ-424 Document Management» and «SQ-425 Record Management») to confirm the compliance with the requirements of the present Quality Manual.

4.2.4. Control of Documents

«Auriga» manages QMS documents in accordance with the developed document «SQ-424 Document Management».

4.2.5. Control of Records

Records are made and maintained in usable conditions in accordance with the procedures and standards of «Auriga».

«Auriga» documents procedures for the specification of record management tools in «SQ-425 Record Management».

Records containing information about health are not used by «Auriga» in the process of work.

Record identifiability, clarity, and restorability and longevity of storage are determined in «SQ-425 Record Management».

5. Management Responsibility

5.1. Management Commitment

Senior management of «Auriga» provides evidence of its commitment to the development and implementation of QMS and the maintenance of its efficiency by:

- bringing to the attention of the organization the importance of fulfilling customer requirements, using the documents in the system of version control, email, chat (Skype, Zoom), telephone conversations, webinars (Zoom), face-to-face meetings;
- developing quality policy;
- ensuring the development of quality objectives;
- conducting management reviews;
- providing necessary resources.

5.2. Customer Focus

Senior management ensures the determination and implementation of all customer requirements and applicable regulatory requirements of the tested MD, which is confirmed by the presence of the procedure «PS-72 Customer-related Processes - Presale», evidence of the fulfillment of the established requirements.

5.3. Quality Policy

Senior management ensures the development and fulfillment of quality policy requirements:

- compliance with the strategic intentions of the organization;
- obligation to comply with QMS requirements and to maintain its efficiency;
- provision of a framework for establishing and reviewing quality objectives;
- informing staff of the organization and ensuring their comprehension;
- ongoing aptitude analysis.

The procedure of development and official approval of the quality policy is determined in the standard «SQ-424 Document Management».

The quality policy is issued as a separate document and is distributed to all divisions.

5.4. Planning

5.4.1. Quality Objectives

Senior management of «Auriga» ensures the quality objectives are set for the relevant functions and on the relevant level within the organization. Quality objectives are measurable and comply with the quality policy.

The procedure of quality objective development is determined in the standard «SQ-424 Document Management».

Standard «SQ-424 Document Management» contains the link to the location of the quality objectives.

5.4.2. Quality Management System Planning

Senior management ensures:

- QMS planning to fulfill the requirements, stated in Section 4.1, and to achieve quality objectives;
- preservation of QMS integrity in the process of planning and implementing changes.

Planning of the QMS is conducted within the frame of management review according to «PQ-56 Management Review» through the specification of quality objectives.

Planning of the QMS beyond the «Management Review» process is conducted under the written instruction of the General Director. The plan and records of its execution are contained in the «General» catalog located on the level of the base folder QMS.

5.5. Responsibility, Authority, and Communication

5.5.1. Responsibility and Authority

Senior management ensures the determination and documentation of responsibility and authority in the work instructions.

Senior management ensures employee awareness of responsibility and authority with the help of documents in the system of version control and email.

Senior management documents the interaction of employees, managing, executing, and verifying the work of quality assurance, and provides the authority and independence necessary for execution of these tasks in the «Regulations on Departments».

The procedure of the development of work instructions and regulations on departments is described in the standard «SQ-424 Document Management».

The list of processes and their proprietors is located in the «QMS Process Diagram».

5.5.2. Management Representative

Senior management assigns the management representative from the management in the «Decree on QMS Development and Implementation», which independently from other responsibilities has the responsibility and authority, including:

- ensuring that processes needed for the QMS are documented;
- spreading comprehension of QMS requirements within «Auriga»;
- reporting to senior management about the efficiency of the QMS and the necessity for improvement.

Management is performed through functional subordination of process proprietors to the management representative.

5.5.3. Internal Communication

Senior management provides the development of the relevant processes of information exchange in «Auriga», including issues on QMS efficiency, using the documents in the system of version control, documents in network folders, email, chat (Skype, Zoom), telephone conversations, webinars (Zoom), and face-to-face meetings.

5.6. Management Review

5.6.1. General

«Auriga» documents procedures for management review in «PQ-56 Management Review». Senior management analyzes the QMS to ensure its continuous usability, adequacy, and efficiency in the planned documented intervals. The analysis includes the evaluation of possibilities for improvement and the necessity of making changes to the QMS of «Auriga», including the quality policy and quality objectives.

Records of the analysis from the management side are maintained in usable conditions according to «PQ-56 Management Review».

5.6.2. Review Input

Input data for management review includes statistics and data analysis of:

- feedback;
- claim settlement;
- audits;
- process monitoring and measurement;
- product monitoring and measurement;
- corrective actions;
- preventive actions;
- changes that could influence the QMS;
- recommendations on improvement.

5.6.3. Review Output

Output data of management review is registered according to «PQ-56 Management Review», and it includes the analyzed input data and any decisions and actions related to:

- improvements necessary for maintaining the usability, adequacy, and efficiency of the QMS and its processes;
- product improvement according to customer requirements;
- the need in resources.

6. Resource Management

6.1. Provision of Resources

«Auriga» determines and provides resources necessary for QMS implementation and efficiency maintenance and for meeting the applied regulatory requirements and customer requirements.

6.2. Human Resources

«Auriga» documents the processes of:

- determining competence of employees («PQ-62 Human Resources - Hiring» and «PQ-62 –Human Resources - Appraisal»);
- training («PQ-62 –Human Resources - Training» and «PQ-62 –Human Resources - Adaptation»);
- ensuring employee awareness of the requirements («PQ-72 Customer-related Processes - Presale» and «PQ-71 Planning»).

«Auriga» determines the necessary competence of employees executing the work and influencing product quality in the procedure «PQ-62 Human Resources - Recruitment» and employee job description.

«Auriga» provides preparation for achievement or maintaining the necessary competence in the procedures «PQ-62 Human resources - Training» and «PQ-62 Human Resources - Adaptation».

«Auriga» evaluates the efficiency of the measures taken in the procedures «PQ-62 Human Resources - Training», «PQ-62 Human Resources - Adaptation», and «PQ-62 Human Resources - Appraisal».

«Auriga» ensures employees' awareness of the relevance and importance of their activity and contribution to achieving quality objectives in accordance with the procedure «PQ-56 Management Review», the standard «SQ-424 Document Management», and the procedure «PQ-71 Planning».

«Auriga» maintains in usable conditions the records of employees' education, preparation, skills, and experience in accordance with the procedures «PQ-62 Human Resources - Training», «PQ-62 Human Resources - Adaptation», «PQ-62 Human Resources - Appraisal», and «PQ-62 Human Resources - Hiring».

6.3. Infrastructure

«Auriga» documents the infrastructure requirements necessary for fulfilling requirements according to the procedures «PQ-71 Planning» and «PQ-63 Infrastructure».

The activity of «Auriga» does not imply product entanglement but includes data storage, which is described in the standard «SQ-424 Document Management».

Technical maintenance requirements are specified in the process of project planning according to the procedure «PQ-71 Planning». Requirements are fulfilled according to the procedure

«PQ-63 Infrastructure». «Auriga» documents technical maintenance activity requirements according to the procedures «PQ-71 Planning» and «PQ-63 Infrastructure».

Production environment management requirements are specified in the procedure «PQ-64 Management of Customer Property and Production Environment».

«Auriga» maintains in usable conditions the records on infrastructure in accordance with «PQ-63 Infrastructure» and «PQ-64 Management of Customer Property and Production Environment».

6.4. Work Environment and Contamination Control

6.4.1. Work Environment

«Auriga» documents the production environment requirements necessary for achieving conformity to product requirements according to «PQ-64 Management of Customer Property and Production Environment».

«Auriga» documents the procedure for the monitoring and management of the production environment in «PQ-64 Management of Customer Property and Production Environment».

«Auriga» does not document requirements for employees' medical condition, cleanliness, or clothing, as contact between employees and the product or production environment cannot influence the safety of an MD or its functional characteristics.

«Auriga» takes measures to allow equipment access only for competent persons or others in their presence: laboratory access is restricted according to the procedures «PQ-71 Planning» and «PQ-64 Management of Customer Property and Production Environment»).

6.4.2. Contamination Control

Product contamination is not applicable to the activity of «Auriga».

7. Product Realization

7.1. Planning Product Realization

«Auriga» plans and develops the processes necessary to product realization as described in the documents «QMS Process Diagram» and «PQ-71 Planning». Planning product realization processes complies with the requirements of other QMS processes, as described in the document «PQ-71 Planning».

The organization documents risk management processes in the product realization processes in the standards «*PQ-71 Risk Management*» and «*PQ-71 Project Risk Management*».

Records of risk management are maintained in usable conditions as described in the standards «*PQ-71 Risk Management*» and «*PQ-71 Project Risk Management*».

While planning product realization processes, «Auriga» establishes:

- quality objectives, which are determined by the goals of the engineering department;
- product requirements in the document «Project Plan»;
- the necessity of process and document development (as well as providing resources for exact products, including infrastructure and production environment, in the document «Project Plan»);

- necessary activity on the verification, validation, monitoring, control and testing, storage, and traceability of exact products as well as product acceptance criteria in the document «Project Plan»;
- records necessary to confirm that product lifecycle processes and the final product conform to the requirements of the standard in the document «SQ-425 Record Management».

7.2. Customer-related Processes

7.2.1. Determination of Requirements Related to Product

«Auriga» determines customer requirements, including delivery and post-delivery requirements, according to «PQ-72 Customer-related Processes – Presale».

«Auriga» determines the requirements not specified by the customer but necessary for definite or anticipated usage, when they are known, according to «PQ-72 Customer-related Processes – Presale».

«Auriga» determines applied regulatory requirements related to customer MD according to «PQ-72 Customer-related Processes – Presale».

«Auriga» does not conduct user training, as it is not applicable to the work results of the company.

«Auriga» determines any other additional requirements specified by the customer according to «PQ-72 Customer-related Processes – Presale».

7.2.2. Review of Requirements Related to Product

«Auriga» analyzes requirements before signing the contract and ensures their fulfillment in accordance with «PQ-72 Customer-related Processes – Presale»:

- determining and documenting product requirements;
- complying with the requirements of the contract or order that are different from those previously established;
- the ability of the organization to fulfill the requirements.

«Auriga» maintains in usable conditions the records of the analysis results of requirements and subsequent actions arising from requirement analysis according to «PQ-72 Customer-related Processes – Presale» and manages records in accordance with «SQ-425 Record Management».

Before signing the contract, «Auriga» confirms from the customer the fact of not presented documented requirements according to «PQ-72 Customer-related Processes – Presale» (e.g., withholding information on product risks, unavailability of technical information necessary for presale).

If the product requirements change, «Auriga» ensures the update of the relevant documents and informs the necessary employees of the changed requirements according to «PQ-72 Customer-related Processes – Presale».

7.2.3. Communication

«Auriga» plans and documents the measures for customer communication:

- in the procedure «PQ-71 Planning» for product information;

- in the procedure «PQ-72 Customer-related Processes – New sales» for processing requests, contracts, or orders, including changes;
- in the procedure «PQ-82 Monitoring and Measurement – Feedback and Claim Settlement» for feedback with the customer, including customer claims.

«Auriga» does not document measures on maintaining communication connected with explanatory notices, as it is not related to the work results of «Auriga».

«Auriga» is not the producer of MD and does not maintain connections with regulatory authorities.

7.3. Design and Development

7.3.1. General

«Auriga» documents the procedures of test design and automation in «PQ-73 Design and Development – Test Automation» and «PQ-73 Design and Development – Test Design».

7.3.2. Design and Development Planning

«Auriga» plans test design and automation in accordance with the procedure «PQ-71 Planning» and manages test design and development in accordance with the procedure «PQ-71 Planning».

If necessary, «Auriga» maintains and updates the documentation on planning test design and automation in the process of testing service provision, as described in «PQ-71 Planning».

In the process of planning test design and automation, «Auriga» documents:

- the schedule of test design and automation for each project on testing in «Project Plan»;
- required actions on the analysis of test design and automation according to the procedure «SQ-84 Data Analysis»;
- required actions on the verification and validation of test design and automation for each project on testing in «Project Plan» and «Testing Strategy»;
- the responsibility and authority of employees for each project on testing in «Testing Strategy»;
- the traceability of output data to input data, which is ensured by procedures «PQ-73 Design and Development – Test Automation» and «PQ-73 Design and Development – Test Design»;
- resource requirements, including competence of employees for each project on testing, in «Project Plan» and «Testing Strategy».

7.3.3. Design and Development Inputs

«Auriga» determines input data related to product requirements, on the stage of planning, according to «PQ-71 Planning» and maintains the records in usable conditions according to «PQ-71 Planning».

«Auriga» uses input data for test design and automation:

- functionality requirements;
- applicable MD regulatory requirements and standards applied to MD (also requirements);

- applicable output data on risk management;
- information obtained from previous analogous projects, if feasible;
- other requirements important for the design and development of products or processes.

«Auriga» analyzes input data for adequacy and officially approves it within the framework of the planning process according to the procedure «PQ-71 Planning».

7.3.4. Design and Development Outputs

According to the procedures «PQ-73 Design and Development – Test Automation» and «PQ-73 Design and Development – Test Design», «Auriga» determines output data of design and development, maintains the records in usable conditions, and fulfills the following requirements:

- to conform to the input data of design and development;
- to provide the necessary information related to purchasing, production, and service.

«Auriga» defines the criteria of product acceptance and specifies the product characteristics on the stage of planning in connection with the specificity of the provided service on SW testing for MD. Product acceptance criteria and characteristics are described in the planning procedure «PQ-71 Planning» and are fixed in the «Project Plan».

Output data of design and development are presented in a form allowing verification to be performed with regard to input data of design and development, and they are approved before their subsequent usage according to the procedures «PQ-73 Design and Development – Test Automation» and «PQ-73 Design and Development – Test Design».

7.3.5. Design and Development Review

«Auriga» performs systematic design and development analysis in accordance with the planned and documented events (according to «SQ-84 Data Analysis») aiming at:

- evaluation of the ability of design and development results to comply with requirements;
- identification and suggestion of necessary actions.

This analysis is performed by employees of the engineering department.

Records of analysis results and all required actions are maintained in usable conditions, and they include project descriptions within the framework of analysis, involved participants, and dates of analysis according to «SQ-84 Data Analysis».

7.3.6. Design and Development Verification

Design and development verification is performed according to the procedures «PQ-73 Design and Development – Test Automation» and «PQ-73 Design and Development – Test Design» in accordance with the planned events in the «Project Plan» to ensure the compliance of output data of design and development with input data of design and development.

«Auriga» documents verification plans in the «Project Plan» and determines the methods and acceptance criteria of the design and development results in the procedures «PQ-73 Design and Development – Test Automation» and «PQ-73 Design and Development – Test Design».

The records of results and conclusions on verification and required actions are maintained in usable conditions according to «PQ-73 Design and Development – Test Automation» and «PQ-73 Design and Development – Test Design».

7.3.7. Design and Development Validation

Design and development validation is performed according to the procedures «PQ-73 Design and Development - Test Automation» and «PQ-73 Design and Development - Test Design» in accordance with the planned events in the «Project Plan» to ensure the compliance of the final product with requirements for its designated or estimated usage.

«Auriga» documents the validation plans in the «project Plan» and determines the methods and acceptance criteria of the design and development results in the procedures «PQ-73 Design and Development - Test Automation» and «PQ-73 Design and Development - Test Design».

The result of the provided service is not a part of a series; therefore, the validation is performed selectively for different components of the performed work.

Validation is performed before product delivery to a customer.

Records of results and conclusions on validation and necessary actions are maintained in usable conditions according to «PQ-73 Design and Development - Test Automation» and «PQ-73 Design and Development - Test Design».

7.3.8. Design and Development Transfer

Design and development output data transfer happens automatically, as «Auriga» provides services on SW testing for MD. The standard «SQ-425 Record Management» contains all necessary data for the explicit juxtaposition of requirements and developed/automated tests, which presents sufficient input information for the production phase.

7.3.9. Control of Design and Development Changes

«Auriga» documents the process for design and development change management in the procedure «PQ-71 Planning». «Auriga» determines the importance of changes in the existing requirements.

Changes in design and development are identified, analyzed, and recorded to the «Project Plan» and are approved according to the procedure «PQ-71 Planning».

Design and development change analysis includes evaluating the influence of changes to the already-delivered product to input and output data of risk management and product lifecycle processes.

Records of changes, change analysis results, and any necessary activities are maintained in usable conditions according to «PQ-71 Planning».

7.3.10. Design and Development Files

«Auriga» maintains a document provision file of MD testing design and development for each project. That file is determined in the standards «SQ-424 Document Management» and «SQ-425 Record Management».

7.4. Purchasing

7.4.1. Purchasing Process

«Auriga» documents the procedure of purchasing by the standard «SQ-74 Management of Purchasing», providing the conformity if the purchased product to the established requirements to purchasing.

«Auriga» establishes the criteria for evaluating and choosing the supplier according to the standard «SQ-74 Management of Purchasing».

In the process of performing subsequent purchasing, «Auriga» performs the monitoring (market research and analysis of suppliers from the register of trusted suppliers) and reevaluation of suppliers. Monitoring results are formed and used in the process of supplier reevaluation.

Nonfulfillment of the purchased product requirements by the supplier is considered individually in each case and is grounded on the proportion of risk, connected with the purchased product, and the influence on the delivery date and quality of the purchased service.

Records on the results of the evaluation, choice, monitoring, and reevaluation of supplier possibilities or the results of their activity and any necessary actions arising from this activity are maintained in usable conditions according to «SQ-74 Management of Purchasing».

7.4.2. Purchasing Information

Purchasing information describes or contains links to the requirements of the purchased SW or equipment as described in «SQ-74 Management of Purchasing».

«Auriga» ensures the adequacy of the determined purchasing requirements before their communication to the supplier, as described in «SQ-74 Management of Purchasing».

«Auriga» maintains in usable conditions the relevant information on purchasing in the form of documents and records according to «SQ-74 Management of Purchasing».

7.4.3. Verification of Purchased Product

«Auriga» only performs entrance visual inspection of the purchased SW (SW holder) or equipment to ascertain purchased or ordered product conformity as described in «SQ-74 Management of Purchasing».

In the case of a nonconforming product, «Auriga» exchanges the purchased product from the supplier or performs other actions described in «SQ-74 Management of Purchasing».

Verification activity on the supplier premises is not applicable due to:

- the nature of the activity of «Auriga» (SW testing for MD);
- supplier guarantees on the delivered equipment or SW;
- the fact that purchased SW or equipment cannot be a part of a MD.

Records on verification are maintained in usable conditions according to «SQ-74 Management of Purchasing».

7.5. Production and Service Provision

7.5.1. Control of Production and Service Provision

«Auriga» plans test execution according to the procedure «PQ-71 Planning», conducts test execution according to the procedure «PQ-75 Production and Service - Test Execution», and monitors and controls the results of test execution according to the procedures «PQ-75 Production and Service – Test Execution» and «SQ-84 Data Analysis» (to provide product conformity to the specifications).

«Auriga» manages production conditions applicable to the provided testing services:

- evaluation of whether infrastructure quality level meets the requirements of the project is conducted in the process of equipment exploitation by employees of «Auriga». When

problems with infrastructure arise, the employees report the problem according to the procedure «PQ-63 Infrastructure»;

- monitoring and measurement of process parameters is done according to «PQ-63 Infrastructure» and «PQ-64 Management of Customer Property and Production Environment»;
- availability of equipment for monitoring and measurement is determined according to the procedure «PQ-64 Management of Customer Property and Production Environment».

«Auriga» provides unique services; therefore, traceability (in accordance with Section 7.5.9) is ensured by the procedure «PQ-75 Production and Service – Test Execution».

7.5.2. Cleanliness of Product

Product purity is not applicable to the activity of «Auriga».

7.5.3. Installation Activities

Installation activities are not applicable to the activity of «Auriga».

7.5.4. Servicing Activities

«Auriga» documents its obligations on maintaining testing results in the «Project Plan» according to the procedure «PQ-71 Planning» if these obligations are a part of the customer contract.

«Auriga» performs the following tasks related to maintaining testing results:

- testing activities according to the procedures «PQ-73 Design and Development – Test Automation», «PQ-73 Design and Development – Test Design», and «PQ-75 Production and Service – Test Execution»;
- data analysis and the improvement process according to «PQ-82 Monitoring and Measurement - Feedback and Claim Settlement», «SQ-84 Data Analysis», and «SQ-85 Improvement».

«Auriga» maintains the records on maintenance in usable conditions according to the procedures «PQ-73 Design and Development – Test Automation», «PQ-73 Design and Development – Test Design», and «PQ-75 Production and Service – Test Execution», and they are in the «Medical Device Testing Project File».

7.5.5. Particular Requirements for Sterile Medical Devices

The sterility of MD is not applicable to the activity of «Auriga».

7.5.6. Validation of Processes for Production and Service Provision

«Auriga» plans the validation of processes according to the procedure «PQ-71 Planning», conducts the validation of test execution processes according to the procedure «PQ-75 Production and Service – Test Execution», and conducts the validation of service processes according to the procedures «PQ-75 Production and Service – Test Execution», «PQ-73 Design and Development – Test Design», and «PQ-73 Design and Development – Test Automation».

The described procedures, including process validation, undergo analysis according to «SQ-84 Data Analysis» by the criteria described in «SQ-84 Data Analysis» for the procedures «PQ-75 Production and Service – Test Execution», «PQ-73 Design and Development – Test Design», and «PQ-73 Design and Development – Test Automation».

The competency of employees is confirmed by education, work experience, appraisal results, and results of internal and external training of employees in accordance with the procedures «PQ-62 Human Resources – Appraisal» and «PQ-62 Human Resources - Training».

«Auriga» documents the process of the validation of computer SW used in production and service in the standard «SQ-416 Software Usage Validation». This SW is validated before its first usage and, if feasible, after making changes to the SW or its usage. Validation and revalidation activity of SW is proportional to the risk connected with the SW usage, including its influence on product conformity to specifications.

Records of the results and conclusions, as well as any necessary activities on validation, are maintained in usable conditions according to «PQ-75 Production and Service – Test Execution», «PQ-73 Design and Development – Test Design», «PQ-73 Design and Development – Test Automation», and «SQ-416 Software Usage Validation».

7.5.7. Particular Requirements for Validation of Processes for Sterilization and Sterile Barrier Systems

The sterility of MD is not applicable to the activity of «Auriga».

7.5.8. Identification

«Auriga» identifies the results of executed work according to the standard «SQ-425 Record Management».

«Auriga» identifies the status of testing work with the help of tasks in JIRA according to the procedures «PQ-73 Design and Development – Test Design», «PQ-73 Design and Development – Test Automation», and «PQ-75 Production and Service – Test Execution» in reference to the requirements of monitoring and management, according to the standard «SQ-84 Data Analysis» throughout test execution and maintenance.

7.5.9. Traceability

7.5.9.1. General

«Auriga» provides traceability of records on test execution according to the procedure «PQ-75 Production and Service – Test Execution», which are maintained in usable conditions according to «PQ-75 Production and Service – Test Execution».

7.5.9.2. Particular Requirements for Implantable Medical Devices

Requirements for implanted MD are not applicable to «Auriga».

7.5.10. Customer Property

«Auriga» identifies, verifies, protects, and preserves customer property provided for usage while it is under the supervision of «Auriga» or is being used by «Auriga» as described in the procedure «PQ-64 Management of Customer Property and Production Environment». If a

customer's property is lost or damaged or is declared unusable, the customer is notified, and the records are maintained in usable conditions according to «PQ-64 Management of Customer Property and Production Environment».

7.5.11. Preservation of Product

«Auriga» documents the procedure on product conformity to the requirements in the process of production and storage in the standard «SQ-424 Document Management».

7.6. Control of Monitoring and Measuring Equipment

«Auriga», in cooperation with the customer, specifies the necessary monitoring and measuring necessaryto ensure the evidence of product conformity to the established requirements. Records of that are placed in the «Project Plan» in accordance with the procedure «PQ-71 Planning».

«Auriga» documents the procedure «PQ-64 Management of Customer Property and Production Environment» to ensure that monitoring and measurement can be done in accordance with the requirements to monitoring and measurement of product and production environment (specifically the availability of calibrations).

According to «PQ-64 Management of Customer Property and Production Environment», «Auriga» provides the following for measuring devices:

- calibration and/or checking in the specified periods;
- identification of the calibration status;
- protection from damage and deterioration during exploitation, maintenance, and storage.

To provide maintenance of measuring equipment, the procedure «PQ-63 Infrastructure» is also used for the configuration of the computer network to which the equipment is connected.

«Auriga» does not conduct its own calibration and checking of monitoring and measuring equipment but has companies that have the relevant certificates of accreditation perform these tasks. In this regard, indications of equipment during the period of calibration and checking are considered trustworthy.

The records of calibration results are maintained in usable conditions according to the procedure «PQ-64 Management of Customer Property and Production Environment».

«Auriga» documents the process of computer SW validation used for monitoring and measurement in the standard «SQ-416 Software Usage Validation». This SW is validated before its first usage and, if feasible, after making changes to the SW or its usage. The activity connected with validation and revalidation of SW is proportional to the risk connected with SW usage and its influence on product conformity specifications.

Records of results and conclusions, as well as any other necessary validation activities, are maintained in usable conditions in «SQ-416 Software Usage Validation».

8. Measurement, Analysis, and Improvement

8.1. General

«Auriga» plans and executes the processes of monitoring, measurement (evaluation), analysis, and improvement necessary for:

- demonstrating product conformity;
- ensuring QMS compliance;
- maintaining QMS efficiency.

8.2. Monitoring and Measurement

8.2.1. Feedback

As a method of QMS efficiency evaluation, «Auriga» collects information related to its meeting of customer requirements and conducts its monitoring in accordance with the procedure «PQ-82 Monitoring and Measurement – Feedback and Claim Settlement».

Methods of obtaining and using this information are documented in the procedure «PQ-82 Monitoring and Measurement – Feedback and Claim Settlement».

«Auriga» documents the procedure on feedback in «PQ-82 Monitoring and Measurement – Feedback and Claim Settlement». The feedback process includes the procedure of data collection at any stage of working with a customer in the engineering department over the period specified in the contract.

Information collected in the feedback process is used as potential input data to risk management with the purpose of monitoring and maintaining requirements for product, improvement, and lifecycle processes.

«Auriga» is not subject to MD regulatory requirements because it does not produce MD but tests SW for MD. Thus, «Auriga» does not accumulate experience based on information obtained over the period specified in the contract.

8.2.2. Complaint Handling

«Auriga» is not subject to MD regulatory requirements because it does not produce MD but tests SW for MD. Nevertheless, «Auriga» documents claim settlement in the procedure «PQ-82 Monitoring and Measurement – Feedback and Claim Settlement». This procedure specifies the requirements and distributes responsibilities related to:

- obtaining and registering information;
- evaluating information to identify whether the feedback represents the claim;
- investigating claims;
- performing actions with testing results, toward which the claim was received (through corrections or corrective actions);
- defining the necessity to initiate corrections or corrective actions.

If a claim is not investigated, the reason is documented in accordance with the procedure «PQ-82 Monitoring and Measurement – Feedback and Claim Settlement». Any correction or corrective action as a result of claim settlement is documented according to the standard «SQ-

85 Improvement». If the investigation shows that the reason for the claim is related to activity outside the organization, the exchange of the corresponding information between the organization and the third party is performed.

Records of claim settlement are maintained in usable conditions in accordance with the procedures and standards of «Auriga».

8.2.3. Reporting to Regulatory Authorities

«Auriga» is not subject to MD regulatory requirements because it does not produce MD but tests SW for MD.

8.2.4. Internal Audit

«Auriga» conducts internal audits at planned intervals to establish that the QMS:

- complies with the planned and documented activities, standard requirements, and QMS requirements developed by the organization;
- is implemented, efficient, and maintained in usable conditions.

«Auriga» documents the procedure «SQ-82 Internal Audit», specifying the responsibilities and requirements related to the planning and execution of audits, records, and reports on audit results.

The program of audits is planned with an account of the status and importance of audit processes and sphere and of previous audit results. Criteria, sphere of application, frequency, and methods of audits are determined according to the procedure «SQ-82 Internal Audit» and are registered in accordance with the procedures and standards of «Auriga». The choice of auditors and audit execution ensures the objectivity and impartiality of the audit process, which is regulated by «SQ-82 Internal Audit».

Records related to audits and their results, including the identification of audit processes and spheres as well as audit conclusions, are maintained in usable conditions in accordance with the procedures and standards of «Auriga».

Management, responsible for the inspected sphere of activity, ensures that any necessary corrections and corrective actions are undertaken in a timely manner to eliminate the detected nonconformity and its causes.

Further activities include the verification of undertaken measures and records of verification results.

8.2.5. Monitoring and Measurement of Processes

«Auriga» applies the methods of process monitoring and measurement (if feasible) of the QMS as described:

- in a separate section in procedures and standards (where available);
- in the standard «SQ-84 Data Analysis».

These methods demonstrate the ability of processes to achieve the planned results. If the planned results are not achieved, which is determined in accordance with the procedure «SQ-84 Data Analysis», corrections and corrective actions are taken according to the procedure «SQ-85 Improvements», if feasible.

8.2.6. Monitoring and Measurement of Product

«Auriga» conducts the monitoring and measurement of product characteristics to verify product conformity to the determined requirements as described:

- in the separate section of procedures and standards (where available);
- in the standard «SQ-84 Data Analysis».

Monitoring and measurement of product characteristics is conducted at the corresponding stages of product lifecycle processes and in accordance with the planned and documented activities as well as documented procedures by the standard «SQ-84 Data Analysis».

Evidence of compliance with the acceptance criteria is determined in accordance with the procedure «PQ-71 Planning» and maintained in usable conditions in accordance with the standards and procedures of «Auriga». The records indicate the person authorizing the product release from the customer side. If determined by the «Project Plan», the records identify the equipment used for measurement.

Production and service are carried out after the successful completion of planned and documented events, which is recorded in the «Project Plan» in accordance with the procedure «PQ-71 Planning».

8.3. Control of Nonconforming Product

8.3.1. General

«Auriga» provides identification and management of product that does not conform to the requirements for the purpose of the prevention of unintended product delivery in accordance with the standard «SQ-83 Management of Nonconforming Product». «Auriga» manages nonconforming product in accordance with the standard «SQ-83 Management of Nonconforming Product», defining the management tools, responsibility, and authority for the identification, documentation, and evaluation of the nonconforming product. The processes of separating and placing nonconforming product do not apply to product of «Auriga», because the service is not mass and does not require space for separate placement.

Evaluation of nonconformity includes investigation within the frames of nonconformity analysis, if it is necessary, and the notification of an external party (if necessary) within the frames of nonconformity analysis according to the standard «SQ-83 Management of Nonconforming Product».

Records of nonconformity and any further undertaken activities, including evaluation, any result of nonconformity analysis (can include investigation), and justification of decisions, are maintained in usable conditions in accordance with the procedure «SQ-83 Management of Nonconforming Product».

8.3.2. Actions in Response to Nonconforming Product Detected Before Delivery

«Auriga» takes the following actions in response to nonconforming products:

- undertakes actions in accordance with standard «SQ-85 Improvement» aimed at
    - the elimination of the detected nonconformity;
    - the prevention of its initial expected usage or implementation;
- postpones the decision for nonconformity or leaves the nonconformity in the product with minor deviations from the established requirements.

«Auriga» accepts nonconforming products only with documented confirmation of customer acceptance within the framework of communication with the customer, planned in the «Project Plan» according to the procedure «PQ-71 Planning».

8.3.3. Actions in Response to Nonconforming Product Detected After Delivery

If a nonconforming product is revealed after delivery, «Auriga» takes actions in the period of support if it is provided by the contract and specified in the «Project Plan». These actions comply with the consequences or potential consequences of nonconformity.

Records of the undertaken actions are maintained in usable conditions as described in «SQ-83 Management of Nonconforming Product».

«Auriga» is not subject to MD regulatory requirements because it does not produce MD but tests SW for MD. In this regard, the use of explanatory notices does not apply to the activity of «Auriga».

8.3.4. Rework

«Auriga» performs alterations of completed work if it is stated in the contract and the «Project Plan». Alterations in that case are described by the same processes as applied to the main activity execution. Therefore, a special procedure for alterations is not required.

8.4. Analysis of Data

«Auriga» documents the procedure of definition, collection, and analysis of the corresponding data in the standard «SQ-84 Data Analysis» to demonstrate the usability, adequacy, and efficiency of the QMS.

This procedure includes the specification of the suitable methods of analysis, including statistical methods contained in the MS Office SW and the area of their application.

The data includes information obtained as a result of:

- monitoring and measurement;
- feedback;
- compliance with product requirements;
- characteristics and tendencies of processes and products, including possibilities of improvement.

If data analysis shows that the QMS is not usable, adequate, or efficient, «Auriga» uses that analysis for:

- nonconformity identification in accordance with «SQ-83 Management of Nonconforming Product»;
- customer claims, considered in accordance with «ПQ-82 Monitoring and Measurement – Feedback and Claim Processing».

Further data analysis results are used as input data for improvement in accordance with «SQ-85 Improvement».

Records of data analysis results are maintained in usable conditions according to standard «SQ-84 Data Analysis».

8.5. Improvement

8.5.1. General

«Auriga» identifies and implements any changes necessary for providing and maintaining the permanent usability, adequacy, and efficiency of the QMS, as well as the safety of the functional characteristics of MD, using the quality policy, quality objectives, audit results, data analysis, corrective and preventive actions, and management review.

8.5.2. Corrective Actions

«Auriga» undertakes actions aimed at the elimination of nonconformity causes to prevent their repeated occurrence. Any necessary corrective actions are undertaken within an appropriate time frame. Corrective actions are proportional to the consequences of the revealed nonconformity.

«Auriga» documents the procedure, specifying requirements for:

- nonconformity analysis (including claims) «SQ-83 Management of Nonconforming Product»;
- determination of nonconformity causes;
- evaluation of necessity for actions to prevent repeated nonconformity occurrence.

«Auriga» documents the procedure «SQ-85 Improvement» to specify the requirements for:

- planning and documentation of necessary actions and their implementation, including, if feasible, document actualization;
- efficiency analysis of the undertaken corrective actions, if feasible.

Records of results of any investigation and undertaken actions are maintained in usable conditions according to the relevant procedures and standards.

8.5.3. Preventive Actions

«Auriga» determines the actions aimed at the elimination of potential nonconformity causes for their future prevention. Preventive actions are proportional to the consequences of potential problems.

«Auriga» documents the procedure, specifying requirements for:

- determination of potential nonconformity and its causes «SQ-83 Management of Nonconforming Product»;
- evaluation of necessity for actions to prevent nonconformity occurrence.

«Auriga» documents the procedure «SQ-85 Improvement» to specify the requirements for:

- planning and documentation of necessary actions and their implementation, including, if feasible, document actualization;
- efficiency analysis of the undertaken preventive actions, if feasible.

Records of results of any investigation and undertaken actions are maintained in usable conditions according to the relevant procedures and standards.