




CEVaC Ltd

## QUALITY MANUAL

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## 1. About the organization

### 1.1. Organizational structure

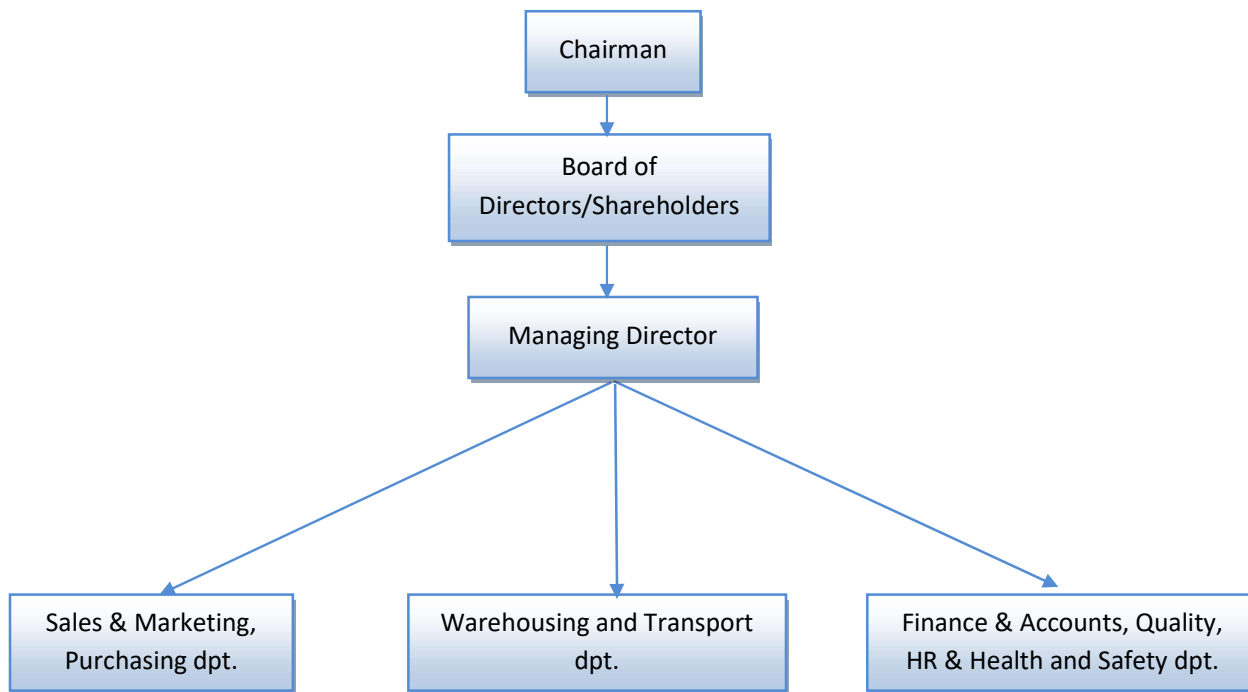


Figure 1: Organizational chart

## 2. Purpose, scope and users

The Quality Manual documents the management system of CEVaC Ltd and demonstrates the capability of CEVaC Ltd to continuously provide products and services that address customer requirements and needs and expectations of interested parties.

### 2.1. Exclusions

CEVaC Ltd excludes the following clauses of ISO 9001:2015:

- 8.3 Design and Development of products and services – CEVaC Ltd does not perform design and development process.

Exclusions do not affect the organization's ability to address customer requirements and appropriate legal and regulatory requirements.

## 3. Terms and definitions

For the purpose of this Quality Manual, CEVaC Ltd references the terms and definitions listed in the ISO 9000:2015 "Quality Management Systems Fundamentals and Vocabulary" document.

The latest revision of this document applies.

## **4. Context of the organization**

### **4.1. Understanding the organization and its context**

CEVaC Ltd considers the context of the organization according to the *Procedure for Determining the Context and Interested Parties*.

### **4.2. Understanding the needs and expectations of interested parties**

CEVaC Ltd has determined the interested parties and their needs and expectations according to the *Procedure for Determining the Context and Interested Parties* and listed them in the *List of Interested Parties*.

### **4.3. Determining the scope of the Quality Management System**

CEVaC Ltd has determined the boundaries and applicability of the Quality Management System in the *Scope of Quality Management System*.

### **4.4. Quality Management System and its processes**

CEVaC Ltd has established and implemented the QMS, which is maintained and continually improved according to the requirements of the ISO 9001:2015 standard including processes needed and their interactions.

CEVaC Ltd determined the processes needed for the QMS and their application through the organization.

CEVaC Ltd determined required inputs and desired outputs of the processes, criteria and methods needed for effective operation and control of these processes, as well as resources needed and responsibilities and authorities for processes in the *Quality Plan*. Sequences and interactions between the processes are described in Figure 2: Process Map.

During management review, senior management of CEVaC Ltd evaluates processes and makes changes needed in order to ensure that the processes achieve intended results and improve processes and the QMS.

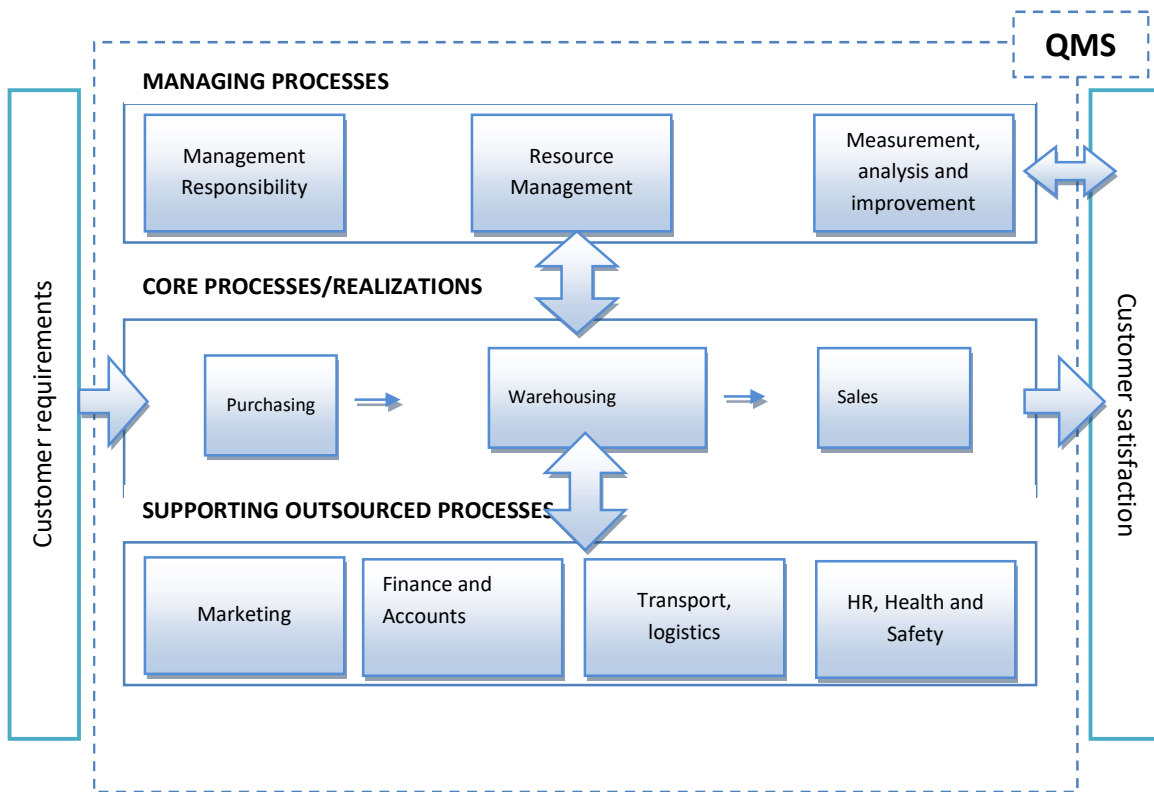


Figure 2: Process Map

## 5. Leadership

### 5.1. Leadership and commitment

#### 5.1.1. General

Senior management of CEVaC Ltd is taking accountability for the effectiveness of the QMS and providing resources to ensure that the **Quality Policy** and **Quality Objectives** are compatible with the strategic direction and the context of the organization.

Senior management ensures that QMS requirements are integrated into CEVaC Ltd's business processes, and that the QMS is achieving the intended results.

Senior management communicates the importance of an effective QMS, promotes continual improvement, a process approach, and risk-based thinking, and supports relevant management roles to demonstrate leadership to their areas of responsibility.

#### 5.1.2. Customer focus

The top management of CEVaC Ltd demonstrates leadership and commitment with respect to customer focus through ensuring:

- that customer and statutory and regulatory requirements are defined, understood, and consistently met
- the risks and opportunities that can affect conformity of products and services and the ability to enhance customer satisfaction are determined and addressed
- the focus on enhancing customer satisfaction is maintained

## 5.2. Quality Policy

CEVaC Ltd has defined the **Quality Policy** as a separate document and made it available to employees and the public.

This Policy represents the framework for planning and improving the QMS, and setting general and specific quality objectives.

## 5.3. Organizational roles and responsibilities

Responsibilities and authorities for relevant roles are assigned by Senior Management and communicated within CEVaC Ltd. Senior management assigns roles and responsibilities for ensuring that the QMS conforms to ISO 9001:2015 and reporting on the performance of the QMS to Senior Management.

# 6. Planning

## 6.1. Actions to address risks and opportunities

While planning the QMS, CEVaC Ltd considers the context of the organization, needs and expectations of interested parties, and the scope of the QMS.

CEVaC Ltd determines risks and opportunities related to the ability to give assurance that the QMS can achieve intended results, enhance desirable results, prevent or reduce undesired effects, is compatible with the context of the organization, and can achieve continual improvement.

Risks and opportunities related to the QMS are addressed according to the **Procedure for Addressing Risks and Opportunities**.

## 6.2. Quality objectives and planning to achieve them

Quality Director continuously defines measurable and timed quality objectives for the relevant functions and levels within the organization. The objectives are monitored by Quality Director in the context of monitoring and measurement and management review.

Quality objectives are consistent with the Quality Policy and prescribed to all levels and functions in CEVaC Ltd, taking into account applicable requirements, relevance to conformity of products and services, and enhancement of customer satisfaction.

The plans for achieving the objective are made for each defined quality objective.

Activities in the plans to achieve quality objectives, responsibilities, deadlines, and resources for the realization of the objectives are defined and documented in the **Quality Objectives**. Realization of

the plans is regularly reviewed by QD in order to monitor realization and to include new or modified situations, or at least during regular management review.

### **6.3. Planning changes**

When the organization determines a need for changes to the Quality Management System, Quality Director takes responsibility to carry them out in a planned manner.

Quality Director plans changes to the QMS considering the purpose of the changes and potential consequences, integrity of the QMS, and allocation or relocation of responsibilities and authorities.

## **7. Resources**

### **7.1. Resources**

CEVaC Ltd determines and provides resources needed for establishment, implementation, maintenance, and continual improvement of the Quality Management System.

### **7.2. Competence**

CEVaC Ltd disposes the necessary staff with the needed knowledge and skills, organizational infrastructure, and financial resources for establishing, implementation, maintenance, and improvement of the QMS.

In cases where it is deemed necessary and justified, CEVaC Ltd will hire competent external personnel and organizations from relevant fields for realization of activities for which the organization does not have adequate resources.

Managers are responsible for identifying the needs and conducting professional training of employees who carry out activities that may have a significant impact on the quality of product, service and customer satisfaction.

Each organizational part manager/process owner is responsible for the suitable competency of his workers, on the basis of education, training, and/or work experience, in accordance with the requirements of their work.

The method of ensuring the necessary competencies for roles, responsibilities, and authorities for implementation and control activities within the QMS was established in accordance with the ***Procedure of Competence, Training and Awareness***. Records of completed training and training effectiveness are kept by the management representative.

### **7.3. Awareness**

CEVaC Ltd ensures that persons doing work under its control are aware of the Quality Policy, relevant quality objectives, their contribution to the effectiveness of the QMS, and implications of nonconformance with the QMS requirements.



## 7.4. Communication

Quality Director is responsible for determining internal and external communications relevant to the QMS, including subject, timing, method of communication, as well as who and with whom will communicate.

## 7.5. Documented information

Documented information of the Quality Management System is carried out through the following documents:

- Quality Policy, Quality Objectives
- Quality Manual
- Procedure for Document and Record Control
- Documents, including records, required by ISO 9001, are given in the ***List of Internal Documents***
- Documents, including records, which CEVaC Ltd has determined to be necessary, are given in the ***List of Internal Documents***

## 8. Operation

### 8.1. Organizational planning and control

Quality Director is responsible for planning and developing processes needed for product realization according to the ***Procedure for Production and Service Provision***.

### 8.2. Requirements for products and services

Communication with customers, the process of determining and reviewing the requirements related to product and services, and changes to requirements for product and services are defined in the ***Sales Procedure***.

### 8.3. Control of externally provided processes, products and services

By documenting an adequate method for evaluation and selection of suppliers, CEVaC Ltd ensures that delivered product is compliant with specified purchasing requests according to the ***Procedure for Purchasing and Evaluation of Suppliers***.

### 8.4. Release of products and services

The organization has implemented planned arrangements, at appropriate stages, to verify that the product and service requirements are met, according to the ***Procedure for Service Provision***.

## **8.5. Control of nonconforming outputs**

The organization ensures that outputs that do not conform to their requirements are identified and controlled to prevent their unintended use or delivery, according to the ***Procedure for Management of Nonconformities and Corrective Actions***.

## **9. Performance evaluation**

### **9.1. Monitoring, measurement, analysis and evaluation**

#### **9.1.1. General**

Quality Director and process owners in CEVaC Ltd define what will be monitored and measured, as well as the methods and timing for monitoring and measuring. Results of the monitoring and measuring will be evaluated at appropriate levels and functions in the organization and the Senior Management will evaluate the performance of the QMS during the management review.

MR is responsible for recording data and measuring and monitoring results that facilitate analysis of corrective actions that follow.

#### **9.1.2. Customer satisfaction**

CEVaC Ltd monitors customers' perceptions of the degree to which their needs and expectations have been fulfilled according to the ***Procedure for Measuring Customer Satisfaction***.

#### **9.1.3. Analysis and evaluation**

CEVaC Ltd analyzes and evaluates appropriate data and information arising from monitoring and measurement.

The results of the analysis are used to evaluate:

- conformity of products and services;
- the degree of customer satisfaction;
- the performance and effectiveness of the Quality Management System;
- if planning has been implemented effectively;
- the effectiveness of actions taken to address risks and opportunities;
- the performance of external providers;
- the need for improvements to the Quality Management System.

### **9.2. Internal audit**

CEVaC Ltd conducts internal audits at planned intervals to demonstrate conformance and effectiveness of the Quality Management System according to the ***Procedure for Internal Audit***.

### **9.3. Management review**

Quality Director of CEVaC Ltd conducts regular reviews of the QMS, at least once a year, according to the *Procedure for Management Review*.

## **10. Improvement**

### **10.1. General**

CEVaC Ltd determines and selects opportunities for improvement and implements any necessary actions to meet customer requirements and enhance customer satisfaction.

These include:

- improving products and services to meet customer and interested requirements, as well as to address future needs and expectations of customer and interested parties;
- correcting, preventing, or reducing undesired effects;
- improving the performance and effectiveness of the Quality Management System.

### **10.2. Nonconformity and corrective action**

CEVaC Ltd handles nonconformities in order to control and correct them and deal with the consequences, according to the *Procedure for Management of Nonconformities and Corrective Action*.

CEVaC Ltd has established a corrective action system to investigate and document the root cause and actions to correct supplier-, internal-, and customer-reported nonconformities. Corrective actions are assigned to a responsible individual and tracked by number and completion date according to the *Procedure for Management of Nonconformities and Corrective Action*.

### **10.3. Continual improvement**

CEVaC Ltd continually improves the suitability, adequacy, and effectiveness of the Quality Management System.

The organization considers the results of analysis and evaluation, and the outputs from management review, to determine if there are needs or opportunities to be addressed as part of continual improvement.