QUALITY MANUAL

ISO 9001:2008
QUALITY MANUAL

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QUALITY MANUAL

PREFACE
The Quality Manual is the overall description of Kraftelektronik AB’s (Kraft) quality management system (QMS) which is made in conformity with the standard SS-EN ISO 9001:2008.

Organization
Kraft is a privately owned company with its head office in Surte, Sweden. Business is done in Surte and Växjö and by subsidiaries in England, Hong Kong and Shanghai. The business in Sweden and Shanghai embraces design, manufacturing and service of products and control systems for power conversion in DC systems, rail vehicles, electrostatic precipitators and electrochemical processes.
4. QUALITY MANAGEMENT SYSTEM

4.1 General requirements
Kraft has identified and established the sequences and interactions of processes needed for the QMS. This is documented in the Enterprise manual (EM) No 75-135.0078, which is assessable on the company’s Intranet.

The QMS has established criteria and methods ensuring that the processes are efficient and are controlled effectively. It also ensures the availability of information necessary to supporting operation and monitoring of these processes. The processes are being measured, monitored and analysed to enable achievement of planned objectives.

4.2 Documentation requirements

4.2.1 General
Kraft’s QMS fulfils all requirements in the standard SS-EN ISO 9001:2008. The quality assurance work is controlled by procedures and instructions. The document No 75-135.0028 describes the structure of the QMS.

All procedures and instructions are available in Swedish.

Customer demands exceeding the content of the QMS may be accepted separate order. Such demands must be clear and fully identified, and they can only be accepted if all affected departments of Kraft have been consulted and give their consent.

4.2.3 Quality manual
This manual gives the over all description of the processes included in the QMS by referring to documented procedures and instructions. The sequence and interaction of the processes included in the system are described briefly in the EM whilst detailed descriptions are included in documents for underlying procedures.

4.2.3 Control of documents
All documents in the QMS affecting the products and their production have revision statues. The documents are controlled and approved by qualified persons prior to distribution.

The instruction IM 22:01 "Procedure document control" indicates who is responsible for issuing and recording of the respective document and for how long time. The records are kept in secure places. IM 22:01 also ensures that all documents regarding manufacturing and testing are available in right editions at the working sites where they are being used.

Document revisions are controlled and approved by the same function that originally approved the document.

4.2.4 Control of records
Records are established and maintained to provide evidence of conformity to the requirements and of the effective operation of the QMS. The control of records is done according to the instruction No 75-135.0059 "Management of records".
KRAFT EMS

Enterprise management

Quality management system
Organisation
Environmental management system

Policies
Objectives

Corrective and preventive actions

Document control
Traceability

Market
Design
Purchasing
Manufacturing
Delivery

Calibration and maintenance of measuring devices

Print-out of documents

HRM = Human resources manual
MMM = Materials management manual
HWS = Health, work environment, safety manual
PM = Production manual
Standard SS-EN ISO 9001:2008

KRAFT QUALITY MANUAL
Over-all description of Kraft’s quality management system.
See www.kraftelektronik.se

KRAFT ENTERPRISE MANUAL
Detailed descriptions of the procedures in the quality and environment systems for the company, departments and functions.
Must not be given out to customers

Kraft Electronics Shanghai Operation Handbook
Description of separate procedures for Kraft Electronics Shanghai.

CUSTOMER DEMANDS

PRODUCT RELATED INSTRUCTIONS
Detailed instructions for the work in manufacturing, testing etc
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克莱夫特(上海)
KRAFT ELECTRONICS SH (KES)

克莱夫特质量文件
Kraft Quality Manual

QA Policy
75-135.0027

KRAFT Organisation Resource management
Q003, Q003-a1, a2, a3, a4, Q023, Q023-a1

文件控制: 质量文件的保存
Document control
Storage of quality documents

识别与可追溯性
Identification & Traceability

不合格产品 / 纠正与防止措施
Non conforming product/ Corrective & preventive actions

文件控制：质量文件的保存
Q004, Q004-a1, Q004-a2, Q028, △ Q035

Q005

识别与可追溯性
Q006, Q006-a1, Q007, Q008

不合格产品 / 纠正与防止措施

定单 设计 采购 生产 测试 交付
Order Design Purchasing Production Testing Delivery
Q002, Q024 Q009 Q010, Q010-a1, Q015 Q016, Q017, Q018, Q018-a1, Q018-a2, Q011, Q012, Q025, Q026A, Q026B, Q027, Q029, Q030, Q031
Q019, Q020-1-7 Q022, Q022-a1, Q022-a2

测量和测试设备的控制
Control of measuring & test equipment
Q013, Q032
5. MANAGEMENT RESPONSIBILITY

5.1 Management commitment
The management has the final responsibility for the quality of the products and services supplied by Kraft.

Kraft’s products shall conform to the relevant standards existing in different market areas. The product quality shall at least fulfil the demands of the standard authorities.

Guidelines for the quality work
All employees at Kraft are responsible for maintaining good quality in products and services. Everyone shall have full competence for his/hers work. This is ensured by all:
- Knowing the requirements on their work
- Having know-how and tools to make the work fault-free
- Aiming at only hand over work in compliance with put up demands
- Making sure faults get analysed and that corrective measures are implemented to ensure that the faults not reoccur.

5.2 Customer focus
The management ensures that customer demands are determined and are met with the aim of enhancing customer satisfaction. The demands are transferred to internal requirements that are communicated to all people involved. Strategic plans are made according to the Enterprise management procedure No 75-135.0069 and activities in sections 7.2.1 and 8.2.1 in this manual.

Customer demands must always be evaluated as to Kraft’s capabilities. Customer orders with conditions that Kraft may not be able to meet must not be accepted.

5.3 Quality Policy
The management has taken a quality policy relevant to Kraft’s business, document No 75-135.0027.

The management ensures that the policy is communicated, understood, applied and maintained by everyone at Kraft by following-up in internal quality audits.

5.4 Planning
5.4.1 Quality objectives
The management annually sets up measurable quality objectives in accordance with the quality policy and relevant to fulfilment of product requirements. The objectives are followed-up at the management reviews. In the minutes from these meetings it is recorded that the objectives have been followed-up and that the actual values have been analysed and decisions taken to improve deviations.

Each manager informs his staff about Kraft’s quality objectives and of the actual situation included decisions for improvement.
5.4.2 Quality management system planning
Plans shall exist to ensure those activities and resources needed are provided for achieving the quality objectives. Plans shall be made for all functions concerned and include their processes and resources necessary. This is described in the Enterprise management document No 75-135.0069.

The quality manager is responsible for maintaining the properties of the QMS when changes have been made in it.

5.5 Responsibility, authority and communication
5.5.1 Responsibility and authority
Kraft is organised with clearly defined areas of responsibility and ways of communication as described in E 02:00 Organisation chart. Responsibilities and authorities are documented in job descriptions for the staff and in matrixes of competence for workers according to procedure No 75-135.0029.

5.5.2 Management representative
The quality manager has the responsibility and authority to make and maintain Kraft’s QMS. In this work he has full support from the managing director.

The quality manager follows-up the efficiency of the QMS and the awareness of customer demands in respective function at Kraft by means of internal audits and analyses of customer complaints. The results from the audits are presented to the management.

5.5.3 Internal communication
Instructions for the internal communication are given in document No 75-135.0072, "communication policy"

The policy, objectives, processes and procedures in the QMS are entered, as originals, on the Intranet. Everybody has access to it and is informed how to find the information. The quality manager is responsible to inform people concerned at system revisions.

5.6 Management review
The management meets biannually, according to routine 75-135.0051, to study and analyse the adequateness and efficiency of the QMS. The reviews are documented by written minutes from the meetings.
1. **QUALITY POLICY**
Kraft shall offer solutions on needs for voltage conversion and control in the customers’ production processes. Kraft’s supply will consequently play an important role for their operation.

Therefore Kraft must only supply products with the right quality. Quality, function, reliability, efficiency and prompt delivery in combination shall constitute Kraft’s competitiveness.

Right quality means that products delivered shall be in compliance with documented requirements in technical specifications and commercial agreements.

All employees at Kraft contribute to the total quality of the products, and each individual is responsible for the quality of his/hers work.

The business shall continuously be improved by systematic development work.

2. **Information on the quality policy**
All employees shall be informed about the quality policy, which is the responsibility of each manager.

3. **Guidelines for the quality work**
The quality is everyone’s responsibility. In order to be able to undertake this responsibility the employees shall have full competence for their work. This shall be accomplished by means that all employees;
- understand the requirements of qualifications for their jobs
- have sufficient knowledge and tools to make the jobs faultless
- only hand over pieces of work that meet the requirements
- make sure that faults occurring will be analysed and that corrective measures will be taken to prevent the faults to reoccur.

Customer orders that may include requirements beyond Kraft’s capabilities must not be accepted. Otherwise there is a risk it will generate bad-will. Therefore customer demands must be evaluated in each case prior to order acknowledgment.

Kraft’s products must be in conformance with relevant standards existing in different market areas. The quality shall at least be of the level that is stipulated by the authorities.

Generally Kraft shall comply with the standard ISO 9001. This includes most of the demands existing in most markets at present.
6 RESOURCE MANAGEMENT

6.1 Provision of resources
Needs for resources in form of people, know-how and equipment are identified in Kraft’s strategic plan. Each manager has to ensure, within his area of command, that there is correspondence between objectives taken on and need of resources. This is normally done in the budgeting process. The procedure “Enterprise management” 75-135.0069 gives the basis for the strategic planning and the budgeting process.

6.2.1 General
All persons making work that affect the product quality shall be properly trained and possess the necessary skills and experience.

Persons executing tasks with special requirement on skill or authority shall be qualified. It is up to managers to ensure this. The qualification shall be based on necessary training and experience. Records shall be kept documenting the training.

The quality manager initiates audits of the QMS and environment management system as well as processes and products. As support, qualified people can assist him.

6.2.2 Competence, awareness and training
All personnel performing work affecting product quality shall have the necessary training. The instruction No 75-135.0032 “Instruction and training” gives the procedure.

Each manager shall, according to the instruction No 75-135.0073, provide for that all subordinated personnel shall possess necessary competence for the work they carry out. The need for training and the planning for it shall be done in connection with the planning talks. These talks between manager and co-workers shall be kept at regular intervals. It is also up to the manager to follow-up that the training has had adequate result.

All employees have been informed on Kraft’s quality policy and they are trained on the parts of the quality system relevant to their work. Each manager shall provide newly employed persons with pertinent information and training.

6.3.1 Infrastructure
Kraft has a well-developed infrastructure to achieve conformity with product requirements.

Manufacturing and testing are done under controlled conditions in premises suitable for Kraft’s business. The areas are in Surte 4680 sqm and in Växjö 800. The premises are being supervised by automatic fire and burglar alarms linked to the fire department and security company. Measures to prevent the risk of fire are described in the procedure No 75-136.0023, “Emergency readiness”.

In order to maintain a well working infrastructure regular inspections are made as well as calibrations and preventive maintenance on equipment and the building. This is described in several instructions in the Enterprise manual.
At Kraft here is a computerised MPS-system acting as information centre for records of articles, specifications of products, procurement, management of production orders and invoicing. The system is described in the MPS manual, which also contains instructions, how to operate in the system. The host computer for the system has an UPS back up and backups of information are taken regularly according to the instruction No E 15:00 “ADB safety”.

When new products are designed attention is given, in the projects, to the manufacturing. The production technique function is responsible for planning how to make the new products and to develop rational work sites.

6.3.2 Work environment
Kraft has a good working environment and has work sites to support accomplishing conformity between the products and existing requirements. The work environment matters are ruled by the management by the “Policy for work environment”, No 75-136.0001.
7. **PRODUCT REALISATION**

7.1 **Planning of product realisation**
This value adding process is overall described in the Enterprise manual. The process is planned and controlled by underlying procedures for each step. The procedures are described in documents accessible on Kraft’s intranet. The management controls and follows-up development of new products in the steering committee “PROST”

7.2 **Customer related processes**

7.2.1 **Determination of requirements related to the product**
Requirements specified by the customer are settled by the sales procedure, IM17:09.

Each product has a documented specification stating technical data, applicable standards, and possible requirements by authorities and customer unique demands etc. This is described in the instruction No 75-135.0037, “Procedure design control”.

7.2.2 **Review of requirements related to the product**
Contract reviews, according to IM 17:09, are made to ensure that agreed terms really can be accomplished.

Kraft reviews every contract draft before acceptance in order to:
- Ensure that the requirements are sufficiently well defined and documented.
- Check that the requirements are in accordance with what has been offered in quotations or similar, possible deviations shall be recorded and discussed with the customer.
- Make clear that Kraft only undertakes requirements possible to fulfil.

The contract reviews are recorded together with the actual C-order in the customer order files.

7.2.3 **Customer communication**
IM 17: 09 describes Kraft’s communications with customers in respect to:
- Product information.
- Questions contracts and alterations.
- Customer response including complaints.

7.3 **Design and development**
Kraft has well planned and controlled procedures for design and development of products. The document No75-135.0037 describes the procedure for design control.

The “Design manual” No 75-135.0041 is an aid for design and development.

7.3.1 **Design and development planning**
There is a documented design plan for every design and development project. The plan is updated at regular intervals during the project.
There is a project leader for each design or development project. He is responsible for coordinating the activities in the project and that pertinent information will be recorded.

7.3.2 Design and development inputs
There is a documented and approved specification on requirements as basis for the design. The specification is made by Kraft or Kraft’s customer.

The design work shall result in a product that satisfies the requirements and is appropriate to manufacture.

7.3.3 Design and development outputs
The outputs from design and development are recorded in files that are kept fire proof. In the instruction No IM 24:04 there are guidelines for making such records.

The project manager is responsible for having necessary documents made for manufacturing and also for customers. This is described in IM 24:03, “Documents for manufacturing”.

7.3.4 Design and development review
Design reviews are planned, made and documented at appropriate stages of the projects involving the relevant persons. The procedure No IM 24:09 describes how this is done.

7.3.5 Design and development verification
A type test is made to verify and validate the design. An instruction for the type test is made with all activities described for verifying the conformant of the product with the requirements in the technical specification. The output is recorded and filed.

7.3.6 Design and development validation
Normally the type test includes both verifying and validation. In certain cases it might be impossible to test the product under defined operation conditions before delivery. Then the validation is done at the customer after accepted verifying in connection with the commissioning. The results are recorded and filed.

7.3.7 Control of design and development changes
Design changes are controlled according to the procedure No 75-135.0037. If the changes affect a vital part of the design a test will be made ensuring the function and quality.

7.4 Purchasing
7.4.1 Purchasing process
The purchasing procedure IM 19:00 ensures that procured products conform with specified requirements.

Kraft will convey to the supplier demands on a necessary Quality Management System.

A thorough evaluation is done of a supplier before he is chosen. Thereafter he is followed-up at regular intervals according to the instruction No IM 19:04 “Choice of supplier”. The supplier’s ability to meet Kraft’s expectations is monitored continuously. If he fails, he will be reminded
and requested to explain his shortcomings and inform about his plans for reaching satisfactory performance. If he still keeps failing Kraft will evaluate the whole situation and most possibly look for alternatives.

There are records on acceptable suppliers. These are kept up-to-date by the purchasing function.

7.4.2 Purchasing information
The purchasing order contains data that clearly and unambiguously defines the product.

The purchasing order is issued accordingly to IM 19:05 “Purchasing data”. The order is examined and approved according to the instruction of authorisation E 02:01.

7.4.3 Verification of purchased product
When receiving purchased materials the procedure for incoming inspection, IM 19:06 is followed. If verification shall take place at the supplier, it shall be stated in the purchasing order, as stated in IM 19:05.

If the Kraft’s customer shall do the verification of a product at a supplier to Kraft, it shall be specified in the purchasing order as stated in IM 19:05.

7.5 Production and service provision
7.5.1 Control of production and service provision
All steps in the manufacturing process, from the first operation to shipment, are planned and controlled. Each manufacturing order contains a list of controlling documents, materials specification and jobs.

The planning is done with support from a computerised MPS-system. Only authorised personnel have access to the system.

Descriptions of instructions and procedures
Product related manufacturing documents exist to ensure that production and testing of products are done in a controlled manner. There are illustrated assembly instructions for each type of product in serial manufacturing. Uncommonly an approved model or pattern could be used. In order to ensure professional workmanship in the products, there is a production manual, No 75-135.0100, containing instructions for general manufacturing methods.

Work force competence
Only workers with sufficient competence will be engaged for jobs where the workmanship is of importance for the quality of the product. Each person engaged in manufacturing and testing has an individual matrix of competence.

Tools and machinery
The production manager has the final responsibility for procurement, maintenance and calibration of the tools and machines used in the production. Preventive maintenance is made on tools and machines in accordance with the instruction No75-135.0148 "Maintenance schedule" to ensure sustainable process efficiency.
Measuring devises
All measuring devises used in verifying measurements are calibrated according to the instruction No 75-135.0104. Documented control and testing instructions state what measurements shall be done and what kind of measuring devises to use.

△ Service
The after sales business is an important part for the customer satisfaction and well functioning products. The procedure 75.135.0040 describes the following provided services:
- Service at site
- Education and training
- Repair in own workshop
- Spare parts deliveries

7.5.2 Validation of processes for production and service provision
We validate all special processes i.e. production processes were the resulting output can not be verified by subsequent monitoring or measurement. These processes are controlled and approved according to well-tried methods and documented in routine 75-135.0034 “Production process control”.

7.5.3 Identification and traceability
The procedure No 75-135.0033 “Product identification and traceability” specifies the control of the traceability. Each product has a rating plate that has a unique identification number. The number is established already at the order stage and accompanies the product through the production process and on to the customer.

Each component has a unique article number and it is recorded in the article register of the MPS-system. Articles to be kept in storage have unique storage places. Sub assemblies made in house like circuit boards, inductors and transformers are also marked with their respective article number.

7.5.4 Customer property
The instruction No 75-135.0050 describes the procedure for handling of products supplied by the customer.
- Material received is evaluated as to function before contract signing.
- Material received is handled and protected in the same manner as our own.
- Damage observed shall be reported to the customer.

7.5.5 Preservation of product
The instruction No 75-135.0036 describes the procedures for handling, storage and protection. Material and products shall be handled carefully to prevent damage from for instance shock, blow or scratches. Semiconductors and printed circuit boards with semiconductors mounted are sensitive to static electricity and must therefore be handled with extra care. This is given in the “ESD instruction”, No 75-135.0105.

Material is kept either in special storage facilities or at the work sites in pallets or racks or similar. It shall be protected adequately to prevent damage or deterioration.
After that a product has been finally tested it shall be kept carefully, against damage prior to shipment.

**Packing and shipment**
Packing is done to protect the product against damage during transport to the customer. The way the packing is done will depend on type of product, means of transportation, destination or special customer requirements.

There is a packing instruction for each standard product according to the procedure No 75-135.0045. Normally it is stated in the customer order what packing is applicable and how the shipment shall be marked.

Before starting packing, the despatch function checks that the product has been tested and approved and that the necessary documents are available. The shipment is marked according so the customer shall be able to identify the goods upon arrival.

**7.5.1 Control of measuring and monitoring devices**
The procedure for calibration and maintenance is given in the instruction No 75-135.0104.

All measuring devises are registered and marked with unique identification numbers and calibration statuses.

All measuring devises used for verifying measurements are regularly calibrated according to the instruction No 75-135.0104 and can be traced to international standards.

If a measuring device deviates from its specification at the calibration, an analysis is made and documented as to the validity of the earlier measurements.

All employees must handle the measuring devises carefully to ensure that their accuracy and usefulness will be maintained.
8. MEASUREMENT, ANALYSIS AND IMPROVEMENT

8.1 General
Monitoring, measurement, analysis and improvement processes needed are planned and implemented to ensure:

- **Conformity to product requirements**
  This is done by controlled final testing on all products based on documented testing instructions with stated criteria for acceptance. The measuring devise used are calibrated according to section 7.5.

- **Conformity to the quality system**
  This is ensured by efficient internal and external audits.

- **Continuous improvement of the effectiveness of the quality system**
  This is done by measures taken that are described in “Continuous improvement”, document No 75-135.0075.

8.2 Monitoring and measurement

8.2.1 Customer satisfaction
Customer satisfaction is measured according to the procedure No 75-135.0079 ”Measurement of customer satisfaction” and by monitoring customer complaints.

The results from the measurements are presented at the management reviews.

8.2.2 Internal audit
The purposes for internal audits are:
- To make sure that documented procedures are being followed and that they are effective.
- To give inputs for improvements.
- To seek for weaknesses in the system.
- To make sure that the requirements of the standard ISO 9001 are met.

The quality manager is responsible for planning, making, documenting, reporting and follow-up the internal audits according to the instruction No 75-135.0024 “Procedure internal audits”. Qualified persons who are independent of the audited function make the audits.

**Reporting and follow-up**
The quality manager follow up all detected nonconformities to verify that corrective actions have been successfully implemented.

The results from the audits are followed-up by the management.

8.2.3 Measurement and monitoring of processes
This is done by inspection and testing during production. In the manufacturing order it is stated which inspection and testing operations shall be made.
All subassemblies are tested, in accordance with the appropriate instruction. Units passing the test are marked with a self-adhesive label “Approved” containing the test person’s employee number. Test protocols are normally not issued.

Crucial production processes are regularly controlled by measurement and analysis of process out-puts as stated in instructions in the Manufacturing manual, No 75-135.0100.

Faults in processes and production methods and deviations from suppliers are measured and monitored according to the procedure No IM 29:04, “Corrective and improving measures”.

8.2.4 Measurement and monitoring of product
All product delivered to customer undergo final testing verifying that specified requirements are met during the entire manufacturing process. The instruction “Inspection, testing and control” No 75-135.0035 gives the procedure.

Testing is made according to the relevant instruction, stated in the production order. The results from the test are documented in the test protocol. After passing the test the product is marked with a label “Approved” including the test persons employee number.

The test protocol is filed together with the actual customer order by the service department. A copy of the test protocol may be given to the customer.

8.3 Control of non conforming product
A product deviating from specified requirements is not approved for delivery, and it must be identified and handled in a controlled manner. IM 29:03 “Handling of nonconforming product” gives the procedure.

Identification and marking of non conforming material
In order to prevent nonconforming material to be used in the manufacturing or be sent to the customer, it will be marked and isolated from the conforming material immediately on detection.

Reporting
All employees are obliged to report the deviations they detect.

Repair or re-work
Defective material must be repaired or re-worked to eliminate the deviation before it may be used. When such material is corrected it shall be subject to re-verification to demonstrate conformity to the requirements.

Remaining nonconformity
Product with nonconformity remaining after corrective measures shall be scrapped or used for different purposes. The decision shall be made jointly by the marketing and production managers. The instruction No IM 29:03 describes the procedure for preventing nonconforming products to be unintentionally released.
Delivery of product with remaining nonconformity
Product with remaining deviation affecting function, performance, interchange ability, or expected lifetime may only be delivered to the customer if he has approved the nonconformity.

8.4 Analysis of data
As basis for continual improvement of the quality system appropriate data is collected and analysed according to the procedure No 75-135.0051 “Management review”. The analysis gives out data on:
- Customer satisfaction
- Conformity to product requirements
- Characteristics and trends of processes and products
- Supplier performance

8.5 Improvement

8.5.1 Continual improvement
Kraft endeavour continuous improvement of the quality system. The efforts are guided in the document No 75-135.0075, “Continual improvement”

The steering committee “KUL” controls and follows-up the work for continual improvements.

8.5.2 Corrective action
The instruction No IM 29:04 describes the procedure for corrective and preventive actions. Corrective actions shall efficiently eliminate systematic errors. All managers are responsible to have corrective made according to what is decided. The measures are followed-up to ensure that the output has the intended effect.

The corrective actions cover the following areas:
- Product performance
- Manufacturing documents
- Production processes and methods
- Non conforming purchased material
- Deviations detected at internal or external audits

8.5.3 Preventive action
Preventive actions are taken to eliminate the causes of potential nonconformities. The appropriate sources of information to detect, analyse and eliminate such causes are:
- Statistics from internal and external audits
- Monitoring customer complaints
- Follow-up on errors in processes and production methods
- Monitoring supplier performance

The data is scrutinised by the management in order to decide on preventive actions needed and monitored to ensure that the actions have intended results.