7.1.1 General

The organization has determined and provided the resources needed for the establishment, implementation, maintenance and continual improvement of the quality management system.

Organization has considered:

a) The capabilities of, and constrains, on existing internal resources;

b) What needs to be obtained from external provides

c) The organization has considered the capabilities of, and constraints on, existing internal resources and what needs to be obtained from external providers.

d) Resource requirements are periodically reviewed by department heads and being discussed with management**.** The following resources are periodically reviewed for capabilities of, and constraints on and what needs to be done also being discussed in management review meeting

7.1.2 People

The organization has determined & provided the persons necessary for effective implementation of its quality management system and for the operation & control of its processes

7.1.3 Infrastructure

Kaizen Engineers determined, provides and maintained the necessary infrastructure necessary for the operation of its processes and to achieve conformity of products and services.

Adequate equipment's for production required to satisfactory realizations of customer requirement (product or service) like co2 welding machine, Press Machine, Drilling machine, Bench Grinder, Tube cutting machine, Shearing machine, Deburring machine, Bending machine, Hand Press, Milling machine, Spot welding machine, Air Compressor, etc. are made available. These machines and equipment are maintained in perfect working condition through periodical preventive maintenance and immediate repairs in the event of break down.

This may include workspace, utilities, process equipment, environment controls, software and supporting services.

Ref: Procedure for Infrastructure Management (OP/MNT/01)

7.1.3.1 Plant, facility, and equipment planning

The organization has used a multidisciplinary approach including risk identification and risk mitigation methods for developing and improving plant, facility, and equipment plans.
In designing plant layouts, the organization has:
a) Optimize material flow, material handling, and value-added use of floor space including control of nonconforming product, and
b) Facilitate synchronous material flow, as applicable.
Methods has been developed and implemented to evaluate manufacturing feasibility for new product or new operations. Manufacturing feasibility assessments included capacity planning. These methods have also been applicable for evaluating proposed changes to existing operations.
The organization has maintained process effectiveness, including periodic re-evaluation relative to risk, to incorporate any changes made during process approval, control plan maintenance, and verification of job set-ups.
Assessments of manufacturing feasibility and evaluation of capacity planning has been inputs to management reviews.

7.1.4 Environment for the Operation of Processes

Kaizen Engineers determined, provides and maintained the necessary Environment necessary for the operation of its processes and to achieve conformity of products and services.
Necessary for the operation of its processes and to achieve conformity of products and services. A suitable environment which includes social (e.g. non-discriminatory, calm, non-confrontational), psychological (e.g. stress-reducing, burnout prevention, emotionally protective), physical (e.g temperature, heat, humidity, light, airflow, hygiene, noise)
In view of the products manufactured and the processes organization has no need of controlled atmospheric conditions.
Suitable work space utilities, safety equipment's & healthy work culture are provided. Housekeeping activities, firefighting equipment first aid facilities are provided. All applicable statutory & regulatory requirements are identified & abided with. Regular Housekeeping review are done to ensure clean, neat, safe & well Organized work areas. Where needed suitable protective methods are utilized
Following are the details of resources identified & provided in the organization to implement, maintain & continually improve QMS & to meet customer requirements resulting in enhancement of customer satisfaction. KE always considers opportunity to enhance plant capability.

Ref: Procedure for Work Environment Management (OP/MNT/02)

7. 1.4. 1 Environment for the operation of processes – supplemental

The organization has maintained its premises in a state of order, cleanliness, and repair that is consistent with the product and manufacturing process needs

7.1.5 Monitoring and Measuring Resources

7.1.5.1 General

The organization has determined and provides the resources needed to ensure valid and reliable results when monitoring or measuring is used to verify the conformity of products and services to requirements.

The organization ensures that the resources are provided:

a) Are suitable for the specific type of monitoring & measurement activities being undertaken;
b) Are maintained to ensure their continuing fitness for their purpose.

The same is being reviewed during Management Review and Minutes of Management Review is maintained as documented information as a evidence of fitness for purpose of the monitoring and measurement resources**.**

7.1.5.1.1 Measurement system analysis

Statistical studies have been conducted to analyse the variation present in the results of each type of inspection, measurement, and test equipment system identified in the control plan. The analytical methods and acceptance criteria used conform to those in reference manuals on measurement systems analysis. Other analytical methods and acceptance criteria may be used if approved by the customer.

Records of customer acceptance of alternative methods have been retained along with results from alternative measurement systems analysis

The requirements apply to all measurement systems included in the control plan. The analytical methods and acceptance criteria used are aligned with the customer requirements and their measurement system analysis. Ref. Process Module No. QMS/PM/14

7.1.5.2 Measurement Traceability

Kaizen Engineers has determined the monitoring and measurement to be taken, and the monitoring and measuring equipment (MME) needed to verify conformity of the product to specified requirements.

The Organization has established processes to ensure that monitoring and measuring is carried out appropriately.

When specified, measurement equipment are calibrated or verified at specified frequency prior to use against standards traceable to national or international standards. The organization ensures that the calibration status is protected at its premises.

When used in the monitoring and measurement of specified requirements, computer software shall be verified and re-verified as necessary.

Ref: Procedure for Control of MME - (OP/QA/01)

7.1.5.2.1 Calibration/verification records

The organization has a documented process for managing calibration/verification records. Records of the calibration/verification activity for all gauges and measuring and test equipment needed to provide evidence of conformity to internal requirements, legislative and regulatory requirements, and customer-defined requirements has been retained.
The organization ensures that calibration/verification activities and records include the following details:

a) Revisions following engineering changes that impact measurement systems;
b) Any out-of-specification readings as received for calibration/verification;
c) An assessment of the risk of the intended use of the product caused by the out-of-specification condition;
d) When a piece of inspection measurement and test equipment is found to be out of calibration or defective during its planned verification or calibration or during its use, documented information on the validity of previous measurement results obtained with this piece of inspection measurement and test equipment can be retained, including the associated standard's last calibration date and the next due date on the calibration report;
e) Notification to the customer if suspect product or material has been shipped;
f) Statements of conformity to specification after calibration/verification;
g) Verification that the software version used for product and process control is as specified;
h) Records of the calibration and maintenance activities for all gauging;
i) Production-related software verification used for product and process control

- Whenever the equipment found out of calibration, the suitable action is taken as follows:
  - Re-inspection of inspected material.
  - Notification to customer, in case of dispatch to customer.
    * Repair / replacement of instrument

7.1.5.3 Laboratory requirements

7.1.5.3.1 Internal laboratory

An organization's internal laboratory facility has defined scope that includes its capability to perform the required inspection, test, or calibration services. This laboratory scope has been included in the quality management system documentation. The laboratory shall specify and implement, as a minimum, requirements for:
a) Adequacy of the laboratory technical procedures;
b) Competency of the laboratory personnel;
c) Testing of the product
d) Capability to perform these services correctly, traceable to the relevant process standard; when no national or international standard(s) is available, the organization defined and implemented a methodology to verify measurement system capability;
e) Customer requirements, if any;
f) Review of the related records

The Kaizen Engineers have in-house laboratory facility only for Voltmeter & Ammeter calibration for Co2 Welding Machine.

7.1.5.3.2 External laboratory

External/commercial/independent laboratory facilities used for inspection, test, or calibration services by the organization have a defined laboratory scope that includes the capability to perform the required inspection, test, or calibration, and either:
The laboratory shall be accredited to ISO/IEC 17025 or national equivalent and include the relevant inspection, test, or calibration service in the scope of the accreditation (certificate); the certificate of calibration or test report includes the mark of a national accreditation body; or there shall be evidence that the external laboratory is acceptable to the customer.

Calibration services may be performed by the equipment manufacturer when a qualified laboratory is not available for a given piece of equipment. In such cases, the organization ensures that the requirements listed in Section 7.1.5.3.1 have been met.

Use of calibration services, other than by qualified (or customer accepted) laboratories, may be subject to government regulatory confirmation, if required**.**

7.1.6 Organizational Knowledge

Kaizen Engineers has determined the knowledge necessary for the operation of its processes and to achieve conformity of products and services.

This knowledge is maintained and be made available to the extent necessary.

When addressing changes needs and trends, the organization has to be considering its current knowledge and determine how to acquire or access any necessary additional knowledge and required updates**.**
The Organization has:

a) Determined the necessary competence of the persons doing work under its control that affects the performance and effectiveness of the quality management system;
a) Ensures that these persons are competent on the basis of appropriate education, training, or experience;
b) Where applicable, take actions to acquire the necessary competence, and evaluate the effectiveness of the actions taken;
c) Retain appropriate documented information as evidence of competence

Ref: Procedure for Employee Development (OP/HR/01)

7.2. 1 Competence – supplemental

The organization has established and maintained a documented process for identifying training needs including awareness and achieving competence of all personnel performing activities affecting conformity to product and process requirements. Personnel performing specific assigned tasks have been qualified, as required, with particular attention to the satisfaction of customer requirements**.**

7.2.2 Competence - on-the-job training

The organization provides on-the-job training (which shall include customer requirements training) for personnel in any new or modified responsibilities affecting conformity to quality requirements, internal requirements, regulatory or legislative requirements; this includes contract or agency personnel.
The level of detail required for on-the-job training has been commensurate with the level of education the personnel possess and the complexity of the task(s) they are required to perform for their daily work.
Persons whose work can affect quality have been informed about the consequences of nonconformity to customer requirements**.**

7.2.3 Internal auditor competency

All Internal Auditors are getting trained and qualified as per ISO 19011 standard's requirements.
List of qualified internal auditors is maintained.
Quality management system auditors, manufacturing process auditors, and product auditors able to demonstrate the following minimum competencies:
a) Understanding of the automotive process approach for auditing, including risk-based thinking;
b) Understanding of applicable customer-specific requirements;
c) Understanding of applicable ISO 9001 and IATF 16949 requirements related to the scope of the audit;
d) Understanding of applicable core tool requirements related to the scope of the audit;
e) Understanding how to plan, conduct, report, and close out audit findings.
Additionally, manufacturing process auditors shall demonstrate technical understanding of the relevant manufacturing process (es) to be audited, including process risk analysis (such as PFMEA) and control plan. Product auditors shall demonstrate competence in understanding product requirements and use of relevant measuring and test equipment to verify product conformity.
Where training is provided to achieve competency, documented information has been retained to demonstrate the trainer's competency with the above requirements.
Maintenance of an improvement in internal auditor competence demonstrated through:
f) Executing a minimum number of audits per year, as defined by the organization; and
g) Maintaining knowledge of relevant requirements based on internal changes (e.g., process technology, product technology) and external changes (e.g., ISO 9001, IATF 16949, core tools, and customer specific requirements).

7.2.4 Second-party auditor competency

As on date, we don't have any scope to do second party Audit and hence this clause is not applicable to us**.**
The Organization has ensured that persons doing work under the organization's control are aware of:

a) The Quality Policy;
b) Relevant Quality Objectives;

c) Their contribution to the effectiveness of the quality management system, including the benefits of improved performance;
d) The implication of not conforming to quality management system requirements.

Awareness of Quality Policy is made by displaying it within the organization at prominent placed including in local language in production area.
Awareness of Quality Objectives in terms of KPI is made by taking respective departmental head's signature on KPI against Quality Objective and KPI Monitoring Chart.
Other required awareness is made during Daily Production Meeting as well as during Management Review Meeting

7.3.1 Awareness – supplemental

The organization maintains documented information that demonstrates that all employees are aware of their impact on product quality and the importance of their activities in achieving, maintaining, and improving quality, including customer requirements and the risks involved for the customer with nonconforming product

Ref: Procedure for Employee Development (OP/HR/01)

7.3.2 Employee motivation and empowerment

The **Kaizen Engineers** has a process to motivate employee to achieve quality objectives, to make continual improvement, and to create an environment to promote innovation. The process includes the promotion of quality and technological awareness throughout the whole organization. (Employee motivation / reward policy guidelines).

The organization has a process to measure the extent to which its personnel are aware of the relevance and importance of their activities and how they contribute to the achievement of the quality objectives.
The Organization has a policy to identify training needs of individuals relevant to the present and anticipated requirements of the stakeholders so as to ensure conformance to the policy, objectives and targets.

7.4 Communication

What	When	with whom	How	Who
Internal Communication				
Quality policy	Permanent	All Employees / Interested parties	Display / Letter / Training	**Proprietor**
Importance of effective QMS	As per Training plan / during Orientation training	All Employees	Training / Display	**Proprietor**
Responsibilities and Authority	During recruitment / Promotion / Department change	Employee	Procedure / Oral / Training	**Proprietor**
Quality objectives	While defining / Once in 6 months	All employees	Procedure / Oral / Training	**Proprietor**
Customer complaint / Feedback	At the time of receipt	Head of the dept. / Resp. process owner	Meeting	**Customer Representative**

EXTERNAL COMMUNICATION				
Information to external providers	Placing purchase order / Quotation collection	Supplier (External provider)	Purchase order / Letter / Email / Oral	**Purchase I/C**
Product information	Enquiry stage	Customer	Email / Website / Catalogue / Letter	**DH MKT & DH QA**
Enquiry, order, amendments	Enquiry review / Order review	Customer	Electronic media / Letter/ oral	**DH MKT**
Customer feedback	Once in a year / After service	Customer	Forwarding customer feedback form	**Proprietor**
Action taken for customer complaints	Once action taken	Customer	Electronic media / Letter/ oral	QA I/C
Status of customer property	As agreed with customer	Customer	Delivery challan / Letter / Email	STORES I/C

7.5 Documented Information

The Organization's Quality management system includes-

- Documented information required by this International Standard.
- Documented Information determined by the organization as being necessary for the effectiveness of the quality management system.

Documentation Structure

The Organization's Quality Management System has four level of documented information structure -

Level 1, Level 2, Level 3, Level 4

Level 1

Quality Manual serves as the apex manual and outlines the structure and general principles of the quality management system.

Level 2

Quality Procedures/ Process Module include, what, why, when, where, who steps are to be performed, by whom, what materials, equipment and documented information is used.

Level 3

Control Plan & Work instructions are being issued for those tasks where it is necessary to describe work method in greater detail.

Level 4

Documented Information, are retained to fulfil provision of objective evidence of quality system compliance

Each documented information which forms a part of quality system is assigned a unique identification no.

The cover page of the quality manual carries the signatures of the reviewing and approving authorities. In addition, the revision status and date of issue are indicated.

A master copy of each of such documented information is maintained separately in a secured place under control for the reference.
One controlled copy each of the manual & procedure is distributed to following personnel
Master Copy: **Proprietor**

The words "MASTER COPY" is stamped on each page in blue.

Controlled Copy No. 1: QMS Representativa & QA Manager

The words "CONTROLLED COPY" is stamped on each page in Red ink to differentiate the controlled copies from uncontrolled ones
This is required to control information that affects quality. This is achieved by ensuring that relevant documented information- both of internal and external origin are reviewed and approved by authorized personnel prior to release, and that all relevant personnel have access to pertinent issues and that revisions receive the same level of authorization as the originals.

A) Document approval and issue

Internally and externally generated Documented Information that underline the quality management system and which require monitoring for revision and distribution are termed as "CONTROLLED COPY"
Master lists are established to identify current revision status of all Documented Information in the Quality system in order to preclude the use of non-applicable or unauthorized copies. Holders of uncontrolled Documented Information do not receive revisions.

The system ensures that the pertinent issues of relevant Documented Information are available and that the obsolete Documented Information is promptly removed from all points of use.
Copies of obsolete Documented Information are identified and retained as necessary to maintain specified trace ability with stamp “OBSOLETE COPY” in Red.

B) Document changes and or modification.

Amended in any Documented Information is subject to review and re-issue by Proprietor.
Reviews and approvals are based on relevant background information.
Documented Information identifies changes where practicable.
More comprehensive details regarding Documented Information control are contained in procedure.

Ref: Procedure for Control of Documented Information. (OP/QMS/02)
Procedure for Document Identification (OP/QMS/03)

7.5.1.1 Quality management system documentation

The organization's quality management system has been documented and include a quality manual, which can be a series of documents (electronic or hard copy).
The format and structure of the quality manual is at the discretion of the organization
The quality manual shall include, at a minimum, the following:
a) The scope of the quality management system, including details of and justification for any exclusions;
b) Documented processes established for the quality management system, or reference to them;
c) The organization's processes and their sequence and interactions (inputs and outputs), including type and extent of control of any outsourced processes;
d) A document (i.e., matrix) indicating where within the organization's quality management system their customer-specific requirements are addressed**.**

7.5.3 Creating & Updating

a) Identification of documented Information:

Quality Management System Manual

XX-XX
XX – Quality Manual
XX - Running Number

Quality Management System Procedure

XX-XX
XX – Procedure Manual
XX - Running Number

Process Module

XX-XX
XX – Process Module
XX - Running Number

Maintained documented Information (Document)

XX-XX-XX

XX –Quality Format

XX- Department

XX - Running number/ Sr. No.

Retained documented Information (Format/Record)

XX-XX/XX/

XX –DEPT

XX - Format

XX – Sr. No

Work Instruction

XX-XX

WI–Work Instruction

XX– Sr. No.

Process Flow Diagram

XX-XX- XX

PFD–Process Flow Diagram

XX- Department

XX–Sr. No.

Review and Approval of documented information

S.No	Description of document	Format	Media	Review	Approval
01	QMS Manual	English	Hard copy / Electronic media/ MS office	QMS Representative	Proprietor
02	Procedure Manual	English	Hard copy / Electronic media/ MS office	QMS Representative	Proprietor
03	Process Manual	English	Hard copy / Electronic media/ MS office	QMS Representative	Proprietor
04	Quality Policy	English	Hard copy / Electronic media/ MS office	Proprietor	Proprietor
05	Department Quality objectives	English	Hard copy / Electronic media/ MS office	Dept. Head	Proprietor
06	Organizational Quality objectives	English	Hard copy / Electronic media/ MS office	QMS Representative	Proprietor
06	Scope of the organization	English	Hard copy / Electronic media/ MS office	QMS Representative	Proprietor
07	Work instructions / Standard operating procedures (if any)	English / Hindii	Hard copy / Electronic media/ MS office	Dept I/C	Process Head
08	Process Flow Diagram	English	Hard copy / Electronic media/ MS office	Dept. Head QA	Proprietor

7.5.3 Control of Documented Information

The QMS Representative ensures that all System Documents are properly identified and controlled.

The various documents are identified with Stamp as follows:

Sr. No.	Description of Document	Seal to be Affixed	Colour
1.	For all Master copies of the all level of documents	**MASTER COPY** (On the front side of the document.)	BLUE
2.	For all controlled copies taken photocopies from master documents.	**CONTROLLED COPY** (On the front side)	RED
3.	Only for master document after revision. (Only for obsolete copies).	**OBSOLETE COPY** (On the front side)	RED
4.	Copies other than controlled copies (Xerox copy of master copy documents).	**UNCONTROLLED COPY AND REFERENCE COPY (NOT TO BE UPDATED)**	RED

- It is the responsibility of the QMSR to ensure that all documents carry a revision status and clear identification. Its circulation is controlled and a record of the current revision status is kept.
- All documents are reviewed and approved prior to use, by a nominated authority, defined in (Ref. Operating Procedure No. **(OP/QMS/02**).
- The nominated authority ensures that the current issues of relevant documents are made available at all locations requiring such documents for the maintenance of system.
- The nominated authority ensures that obsolete documents are removed from all points of issue or use.
- All document changes are reviewed and approved at the original review and approval authority level.
- The personnel performing review and approval have access to, and take notice of, relevant background information when undertaking a review and approval of document changes.
- A Document Master Index identifying the current revision status of documents is prepared, so as to preclude the use of obsolete documents.

Where a new document or change to an existing document is required, any staff member can initiate it. It is reviewed for relevance and, where appropriate, approved and implemented as defined in (Ref. Operating Procedure No **(OP/QMS/02**).

7.5.3.2.1 Record retention

The organization defines, document, and implement a record retention policy. The control of records satisfy statutory, regulatory, organizational, and customer requirements.
Production part approvals, tooling records (including maintenance and ownership), product and process design records, purchase orders, or contracts and amendments are retained for the length of time that the product is active for production and service requirements, plus one calendar year, unless otherwise specified by the customer or regulatory agency.
Master List of Documented Evidence is maintained

7.5.3.2.2 Engineering specifications

All changes as per Customer's Specification are studied. Based on these study internal documents are reviewed and updated. This reviewed is done within ten working days. Record of the date on which each change is implemented in production is maintained. If required by customer PPAP documents are reviewed and updated.

Records:

Sl.No	Record Title	Format No	Retention period	Retention Resp.	Indexing method	Disposition
01	MSA	QA/F/31 & QA/F/33	Till product exist + 1 Year	QA Head	File / Computer	Shred/ Delete
02	List of Measuring Equipment's & Gauges	QA/F/04	Till Rev.	QA Head	File / Computer	Shred/ Delete
03	Instrument History Card	QA/F/06	03 Years	QA Head	File / Computer	Shred/ Delete
04	List of Inspection Fixtures	QA/F/28	Till Rev.	QA Head	File / Computer	Shred/ Delete
05	In-House Calibration/ verification record	QA/F/29	01 Year	QA Head	File / Computer	Shred/ Delete
06	List of production software	QA/F/35	Till Rev.	QA Head	File / Computer	Shred/ Delete
07	Verification record of production software	QA/F/36	Till Rev.	QA Head	File / Computer	Shred/ Delete
08	List of Employees	HR/F/09	Till Rev.	HR Head	File / Computer	Shred/ Delete
09	Competency Matrix	HR/F/11	03 Years	HR Head	File / Computer	Shred/ Delete
10	Training Schedule	HR/F/11	01 Year	HR Head	File / Computer	Shred/ Delete
12	Skill Matrix	HR/F/01	01 Year	HR Head	File / Computer	Shred/ Delete
13	Training Attendance Record	HR/F/05	Till Empl. is in Service	HR Head	File / Computer	Shred/ Delete
14	On-Job Training Record	HR/F/06	Till Empl. is in Service	HR Head	File / Computer	Shred/ Delete
15	List of Auditors	QMS/F/12	Till Rev.	QMSR	File / Computer	Shred/ Delete
16	Employees motivation	--	03 Years	HR Head	File / Computer	Shred/ Delete
17	List of Forms & Formats	QMS/F/07	Till Rev.	QMSR	File / Computer	Shred/ Delete
18	Document change /Modification note	QMS/F/08	Up to Part Active	Mkt. Head	File / Computer	Shred/ Delete