PROQC
INTERNATIONAL
Global Quality Control and Engineering Solutions

ISO 9001:2015
Quality Systems Audit

** Example Report **

North America
+1-813-252-4770

Latin America
+52-1-333-2010712

Europe & Middle-East
+49-8122-552 9590

Asia & Asia Pacific
+886-2-2832-2990

India
+91-120-4291971

Email
info@proqc.com

www.proqc.com

ISO 9001:2015 Quality System Audit

SUMMARY

Rev. 13

Supplier Name	Audit Date	Report No.
XXXXXXXXXXXXXXXXXXXX	XXXXXXXXXXXXX	XXXXXXXXXXXX

SUPPLIER'S INFORMATION		CLIENT'S INFORMATION	
NAME :	XXXXXXXXXXXXXXXXXXXX	NAME :	XXXXXXXXXXXXXXXXXXXX
ADRESS :	XXXXXXXXXXXXXXXXXXXX	ADRESS :	XXXXXXXXXXXXXXXXXXXX
	XXXXXXXXXXXXXXXXXXXX		XXXXXXXXXXXXXXXXXXXX
CITY :	XXXXXXXXXXXXXXXXXXXX	CITY :	XXXXXXXXXXXXXXXXXXXX
COUNTRY :	XXXXXXXXXXXXXXXXXXXX	COUNTRY :	XXXXXXXXXXXXXXXXXXXX
PHONE :	XXXXXXXXXXXXXXXXXXXX	PHONE :	XXXXXXXXXXXXXXXXXXXX
FAX :	XXXXXXXXXXXXXXXXXXXX	FAX :	XXXXXXXXXXXXXXXXXXXX

SUPPLIER'S PERSONNEL PARTICIPATING

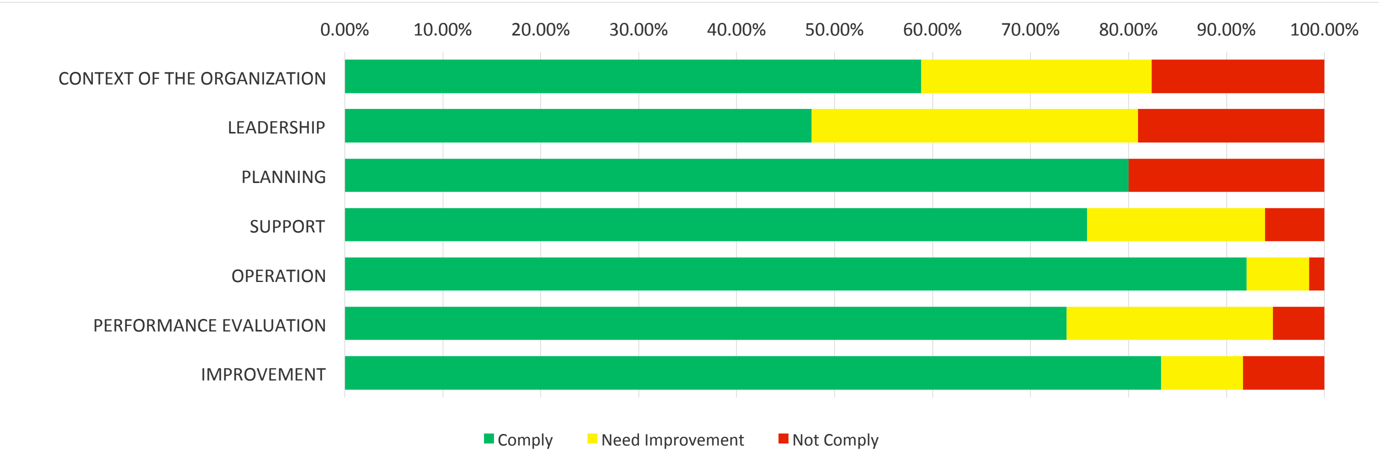
Mr./Mrs.	XXXXXXXXXXXXXXX	Title:	XXXXXXXXXXXXX	Email:	XXXXXXXXXXXXXX
Mr./Mrs.	XXXXXXXXXXXXXXX	Title:	XXXXXXXXXXXXX	Email:	XXXXXXXXXXXXXX
Mr./Mrs.	XXXXXXXXXXXXXXX	Title:	XXXXXXXXXXXXX	Email:	XXXXXXXXXXXXXX
Mr./Mrs.	XXXXXXXXXXXXXXX	Title:	XXXXXXXXXXXXX	Email:	XXXXXXXXXXXXXX
Mr./Mrs.	XXXXXXXXXXXXXXX	Title:	XXXXXXXXXXXXX	Email:	XXXXXXXXXXXXXX
Mr./Mrs.	XXXXXXXXXXXXXXX	Title:	XXXXXXXXXXXXX	Email:	XXXXXXXXXXXXXX
Mr./Mrs.	XXXXXXXXXXXXXXX	Title:	XXXXXXXXXXXXX	Email:	XXXXXXXXXXXXXX

Pro QC PERSONNEL

Mr./Mrs.	XXXXXXXXXXXXX	Title:	XXXXXXXXXXXXXXXXXXXXXXXXXXXXXXX
Mr./Mrs.	XXXXXXXXXXXXX	Title:	XXXXXXXXXXXXXXXXXXXXXXXXXXXXXXX
Mr./Mrs.	XXXXXXXXXXXXX	Title:	XXXXXXXXXXXXXXXXXXXXXXXXXXXXXXX

Scope :

AUDIT RESULTS 82.23%



JUDGEMENT & RECOMMENDATIONS

☐ **Passed**, the QMS is effective, you could consider this supplier a reliable business partner.

☐ **Passed**, the QMS is acceptable with minor NCFs (see **Audit Report**), you consider this supplier a reliable business partner, but push them for improvement to reduce risk.

☒ **On-hold**, the QMS presents few major NCFs (see **Audit Report**), you could request them to provide a CAPA before engaging in any business with them.

☐ **Failed**, the QMS presents serious major NCFs (see **Audit Report**) that could impact upon your business. The better solution would be to source another supplier.

PROQC INTERNATIONAL	ISO 9001:2015 Quality System Audit	Rev.
	AUDIT REPORT	13

Supplier Name	Audit Date	Report No.
XXXXXXXXXXXXXXXXXXX	XXXXXXXXXXXX	XXXXXXXXXXX

Scope of Audit:

The intent of conducting a Quality System audit based on ISO 9001 requirements is to provide the client with information useful for making an initial assessment about business viability, and reducing their sourcing risks.

Summary/Recommendation:

The audited factory XXXXXX is located in Longhua New District of Shenzhen. It is a factory that transforms LED components into LED end products, and was founded in the year 2000.

Each production line is managed by total quality control to ensure the quality of LED production in Operating, Safety, Reliability engineering and Maintainability requirements. So far, XXXXXX has over 50 professional quality control staff and various experimental equipment to maintain high product quality.

The factory XXXXX is certified to ISO 9001:2015, with certificate number XXXXXXX. Their products also meet many different International standards such as UL, CE, ETL, RoHS, REACH, FCC and are approved by International accredited labs like Intertek and TUV

The QMS system audited covers the requirements of ISO 9001:2015, except that KPIs are not totally developed to allow proper monitoring and measuring of the effectiveness of the QMS.

Strengths:

1) Certified to ISO 9001: 2015
2) Highly educated technical staff for design and development of new products
3) Large space in the warehouse and workshop to extend production capacity

Opportunities for Improvement:

4.1 a) Responsibility for communication of external / internal issues must be defined.
4.4 b) Each process must have outputs defined.
4.4 d) Each process must have KPIs defined.
4.4 f) Ownership must be defined for each process.
8.4.2 c) Must have a reaction plan when an external service or product provider has poor performance.
9.2 e) Audit findings must be properly documented, with actions taken.
10.2 g) Risks and opportunities must be updated based on non-conformities found.

PROQC INTERNATIONAL	ISO 9001:2015 Quality System Audit	Rev.
	AUDIT CHECKLIST	13

Supplier Name	Audit Date	Report No.
XXXXXXXXXXXXXXXXXXX	XXXXXXXXXXXX	XXXXXXXXXXX

C = Complies with the requirements, I = Improvement Needed, NC = Not Complies, N/A = Not Applicable

	QUESTIONNAIRE	EVIDENCE	FINDINGS	SCORE
4	**CONTEXT OF THE ORGANIZATION (Clause 4.1, 4.2, 4.3 and 4.4)**			
4.1	**Understanding the Organization and its Context**			
a)	Has the organization identified, documented and analyzed **External issues** that can affect customer satisfaction and delivery of quality products and/or services?	*1) Note Doc. # of list of **External issues** identified that may be: **Legal , Technological, Competitive, Market, Cultural, Social, Economic environment**(Local, Regional, National or International). 2) Note of major external issues identified. 3) Photograph the document.*	Yes, the organization has identified and documented external issues in sheet Doc. #. QM-HW-001-02, Rev A/0. The major issues are: 1) An increase by 20% of new local competitors that provide the same service at the lowest rate (SEE PHOTO 4). 2) The change of new ISO 9001 standard to version ISO 9001: 2015.	**C**
b)	Has the organization identified, documented and analyzed **Internal issues** that can affect customer satisfaction and delivery of quality products and/or services?	*1) Note Doc. # of list of Internal issues identified that may be: Organizational values, culture, knowledge, and performance. 2) Note of major external issues identified. 3) Photograph the document.*	Yes, the organization has identified and documented external issues in sheet Doc. #. QM-HW-001-02, Rev A/0. The major issues are: 1) The level of knowledge of employees that has not been enhanced to meet requirements (SEE PHOTO 4). 2) Stability of employees which is less than 50% compared to what was planned.	**C**
c	Is there an **authority** for the identification, documentation and communication of external / internal issues ?	*1) Photograph the Organizational chart 2) Note name and title of key person in charge of this process. 3) Photograph any record showing that external / internal issues are reviewed, approved and signed by that authority.*	Yes, there is an organizational chart (SEE PHOTO 5). The audited person explained that the GM, Mr. Wang is in charge of this process, but records show that his signature, as evidence that he monitors this process, was missing.	**I**
4.2	**Needs & Expectations of Interested Parties**			
a)	Has the organization identified and documented its **interested parties** relevant to the QMS?	*1) Note Doc. # in which Interested parties are identified such as: Customers, Government & non-government organization, Employees, Shareholders. 2) Photograph the document.*	Yes, the organization has identified and documented interested parties in sheet QM-HW-001-03, Rev A/0 (SEE PHOTO 6): 1) 150 full time employees, salary, insurance. 2) 15 Material suppliers, 3 subcontractors. 3) 26 Clients, 5 of them constitute 80% of business. 4) 2 shareholders with 90% financial support. 5) Local communities (Env. issues) 6) Local government for tax payment.	**C**
b)	Are **needs & expectations** from these interested parties identified and documented?	*1) Review Needs & Expectations. 2) Photograph the document.*	Yes, the organization has documented needs and expectations of each interested party in sheet QM-HW-001-03, Rev A/0 (SEE PHOTO 6):	**C**
c)	Is there an **authority** for the identification and communication of needs & expectations of interested parties?	*1) Photograph the Organizational chart 2) Note name and title of key persons in charge of this process. 3) Photograph any record showing that interested parties are **reviewed**, **approved** and **signed** by that **authority**.*	Yes, there is an Organizational chart (SEE PHOTO 7). The audited person explained that the GM, Mr. Wang is in charge of this process, but records show that his signature, as evidence that he monitors this process, was missing.	**I**
4.3	**Scope of the Quality Management System**			
a)	Has the organization defined the scope of the QMS?	*1) Note the doc number, and Rev in which the scope is defined. 2) Photograph the page.*	Yes, the organization has defined the scope in Doc. # QM-HW-001, Rev. A/0, page 5/ 7 (SEE PHOTO 8)	**C**
b)	Does the scope address external & internal issues, products & services of the organization, and the commitment to apply all applicable requirements of ISO 9001?	*1) Review scope and check for compliance.*	Yes, the organization has defined the scope in Doc. # QM-HW-001, Rev. A/0 which included all those elements.	**C**
c)	If applicable, is the exclusion to the scope properly defined, including its justification	*1) Note the doc number, and page of QM in which the exclusion is defined. 2) Note the clause of ISO 9001:2015 that has been excluded from the organization's QMS. 3) Describe the reason of exclusion*	Yes, the organization has a Quality Manual, Doc. # QM-HW-001, Rev. A/0. The organization does not do Design and Development, so they excluded clause 8.3.	**C**
4.4	**Quality Management System and Process**			

PROQC INTERNATIONAL	ISO 9001:2015 Quality System Audit	Rev.
	AUDIT CHECKLIST	13

Supplier Name	Audit Date	Report No.
XXXXXXXXXXXXXXXXXXX	XXXXXXXXXXXX	XXXXXXXXXXX

C = Complies with the requirements, I = Improvement Needed, NC = Not Complies, N/A = Not Applicable

	QUESTIONNAIRE	EVIDENCE	FINDINGS	SCORE
a)	Are processes needed for the quality management system and their application established and maintained?	*1) Note Doc. # in which processes are mapped / described. 2) Photograph the map that describes their interactions.*	Yes, the organization defines the following 12 processes mapped in sheet QM-HW-001-04 (SEE PHOTO 9): Management Review / Internal Audit / Product Realisation / Purchasing / Incoming Inspection / Maintenance / Employee Training ...etc.	C
b)	Are required **inputs** and expected **outputs** identified and documented?	*1) Verify that each process has **Inputs** and **Outputs** defined. 2) As example select one process, and note his **Inputs** and **Outputs***	10 processes have their inputs and outputs defined, for example of process Internal Audit: 1) Inputs: Audit Plan / certified auditors. 2) Outputs: Audit Result, NC reports …etc. It was noted that 2 processes did not define their outputs such as the process of Purchasing (SEE PHOTO 9)	I
c)	Has the organization determined criteria and methods (WIs, procedures, SOPs) as guidelines tfor implementation of processes?	*1) Verify that each process has defined Procedures / Work Instructions / SOPs 2) As example select one process, and note his **Procedures / WIs defined***	All processes have WIs, Procedures defined, for example of process Internal Audit which use Procedures: QP-12, Rev 2 as guidelines	C
d)	Are criteria and methods monitored, measured, and reviewed through performance indicators? Are there records?	*1) Verify if each process has defined KPIs 2) As an example select one process, and note its **KPIs***	No, processes do not have KPIs defined.	NC
e)	Are resources / equipment needed to obtain planned outputs available and documented in the process.	*1) Verify if each process has necessary resources defined. 2) As example select one process, and note resources*	All processes have resources defined, for example of process production which use machine, assembly line, ERP system ..etc.	C
f)	Is there a documented assignation of responsibilities and authorities to ensure compliance of these processes?	*1) Verify if each process has key owner appointed. 2) As example select one process, and note name / title of the process owner.*	No, ownership is not mentioned in processes	NC
g)	Has the organization identified risks and opportunities for each process (use risk-based thinking) in which possible events or activities will impact the achievement of Quality management objectives?	*Ex. Type of Risk: Sub-supplier does not meet delivery deadline. - Probability: Medium - Impact: High - Mitigation: Sub-supplier is delivering weekly - Contingency: Delivery frequency rating will be provided to sub-supplier.*	No, risk and opportunities for each process are not identified	NC
h)	Are there documented results to evaluate the effectiveness of these processes? Are results reviewed in a timely manner by management?	*1) Check management review 2) Review results 3) Review plan for KPIs*	Management review is conducted on a regular basis once per year, record of the last management review conducted last Dec (12th) are available. However, these records do not show the results and effectiveness of each process since no KPIs were initially planned.	I
5	**LEADERSHIP (Clause 5.1, 5.2 and 5.3)**			
5.1	**Leadership and Commitment**			
5.1.1	**General**			
a)	Can Top Management demonstrate that he is taking accountability for the effectiveness of the quality management system?	*1) Attendee record signed by Top Mgt 2) Management review meeting.*	There are reports of opening / closing meetings with attendance signatures of the Top Management Team. Record of last Management review has the signature of Quality Manager	C
b)	Can Top Management ensure the quality policy and quality objectives are established and compatible with the context and strategic direction of the organization?	*1) Linkage between policy and objectives. 2) Check if this document is reviewed and approved by the Top Mgt*	The document in which policies and related objectives are written and available in sheet QM-WH-010. Evidence such as a signature to demonstrate that it was reviewed and approved by the Top Mgt.	C
c)	Can Top Management demonstrate how they ensure the integration of the quality management system requirements?	*1) Record of Approve of internal audit. 2) Record of opening / closing meeting. 3) Personal resource for QMS*	There are reports of opening / closing meetings with attendance signatures of Top Management Team (See photo 12). The factory has 4 people with Auditor certifications.	C

PROQC INTERNATIONAL	ISO 9001:2015 Quality System Audit	Rev.
	AUDIT CHECKLIST	13

Supplier Name	Audit Date	Report No.
XXXXXXXXXXXXXXXXXXX	XXXXXXXXXXXX	XXXXXXXXXXX

C = Complies with the requirements, I = Improvement Needed, NC = Not Complies, N/A = Not Applicable

	QUESTIONNAIRE	EVIDENCE	FINDINGS	SCORE
d)	Can Top Management demonstrate how they promote the process approach?	*1) Mapping of process and ownership.* *2) Record of Approval of process audit.* *3) Record of opening / closing meeting.*	Processes are mapped and documented, each process has an owner, methods / criteria, inputs / outputs, resources. No KPIs defined for each process. Cannot ensure measurability of the effectiveness of each process.	I
e)	Can Top Management demonstrate how they promote risk-based thinking?	*1) Training on risk-base thinking 2) Encourage proactive action for imp. 3) Record of regular meetings (process base)*	Training about risk-based thinking was scheduled in the annual training program of year 2017, and conducted on 2017-03-17 and 18. All department Managers attended this training. That was recorded on sheet HW-02-12 (See photo 11). However there is no evidence of implementation of risk-based thinking.	I
f)	Can Top Management demonstrate that it has provided resources needed for the QMS?	*1) Manpower, training* *2) Machines, equipment*	Yes, each process identified has an ownership, machines, equipment needed to implement the process and produce expected results.	C
g)	Does Top Management engage, direct, communicate, support, and contribute to achieve the intended quality system results?	*1) Record of Approve of internal audit.* *2) Record of opening / closing meeting. 3) Policies review and approve*	There are reports of opening / closing meetings with attendance signatures of the Top Management Team (See photo 12).	C
5.1.2	**Customer Focus**			
a)	Can Top Management demonstrate how they ensure that customer requirements are determined, understood, and consistently met?	*1) Define process and assign its owner/ leader* *2) Write Procedure Doc. #./ Rev.* *3) Record of order review*	Yes, Top Management has appointment a customer representative whose function is to identify customer requirements, and communicate them internally. A procedure QP-HW-05, Rev A/0 has been documented, and it requires conducting order reviews. Results of reviews are documented on sheet QP-HW-05-02, for example of order number 2071-034 for client XXX conducted in 2017-05-23	C
b)	Does Top Management ensure that risks and opportunities that can affect conformity of products & services, and the ability to enhance customer satisfaction are determined and addressed?	*1) Process map.* *2) Risk / opportunities in each process?* *3) Note example of Risk / opportunities. 4) Related action to address the risk*	Process map exists, no risks and opportunities were identified for each process.	NC
5.2	**Policy**			
5.2.1	**Establishing the Quality Policy**			
a)	Is the quality policy statement appropriate to the purpose and context?	*1) Photograph the place where it was posted.* *2) Evaluate compliance with purpose and context (Interview top management)*	The quality policy is posted in the workplace (See photo).	C
b)	Is the quality policy statement defined in a way allowing for setting and reviewing quality objectives?	*1) Linkage between quality policy & objective* ***2)** Each policy has Quality Objectives and goals been defined.*	The quality policy is established and documented (See photo). Cannot see respective Quality objectives and KPIs.	I
c)	Does the quality policy include commitment to satisfy requirements?		Yes, the quality policy includes commitment to satisfy requirements related to all interested parties.	C
d)	Does the quality policy include commitment to continual improvement of the quality management system?		Yes, quality policy includes commitment to continual improvement of the quality management system.	C
e)	Is there planning to monitor and review Quality Objectives at reasonable intervals?	***1)** Note frequency of review* ***2)** Note current result / trend.* ***3)** Photograph if results are posted.*	Quality objectives and respective KPIs are not defined, so there is no planning of how to monitor and review them.	NC
5.2.2	**Communicating the Quality Policy**			
a)	Is the Quality policy documented or / and posted within the organization?	*1) Photograph if it posted on site*	Quality policy is posted at workplace (See photo).	C
b)	Do staff members understand the Quality Policy?	*2) Interview a few workers.* *3) Any training record*	Record of training of last March 2017. When interviewing senior supervisors, 2 out of 3 do not understand the meaning of the quality policy and how it affect their respective responsibilities.	I

Supplier Name	Audit Date	Report No.
XXXXXXXXXXXXXXXXXXX	XXXXXXXXXXXX	XXXXXXXXXXX

C = Complies with the requirements, I = Improvement Needed, NC = Not Complies, N/A = Not Applicable

	QUESTIONNAIRE	EVIDENCE	FINDINGS	SCORE
c)	Has the quality policy been communicated to each interested parties?	*1) Copies of evidence signed by each interested party.*	There is no copy or evidence attesting that it was communicated to all interested parties. Such a requirement is not documented.	NC
5.3	**Organizational Roles, Responsibilities and Authorities**			
a)	Is there a company Organizational chart with position / title, and does the organizational chart match with the process map to ensure conformance to ISO 9001?	*1) Photograph the Organizational chart (In document or in public board).*	Yes, there is an organizational chart documented in file QM-HW-01-06, Rev A/0 (See photo). Job descriptions are also defined and documented However, found another organizational chart posted in the workshop showing a different job distribution with photo of people that are not in the factory anymore (See photo).	I
b)	Are Job descriptions documented with responsibilities to deliver intended outputs?	*Job Descriptions documented for each process / position of the Organizational chart.*	10 processes have their inputs and outputs defined, with a responsible person / department mentioned, for example of process Internal Audit: 1) Inputs: Audit Plan / certified auditors. 2) Outputs: Audit Result, NC reports …etc. It was noted that 2 processes did not define their outputs such as process Purchasing (SEE PHOTO 9)	I
c)	Are Job description documented with responsibilities to report on performance, and need for change if applicable?	*Process map*	No, processes in the process map did not have KPIs / performance defined	I
d)	Is there a backup person with the same qualification and authority for each possible significant position?	*1) Review the replacement position plan if any, and **take photo.*** ***2) Write the name of backup for Quality Manager, and check if he has a written nomination letter.*** ***3) Ask if Operation people know him as back up for this position.***	No replacement plan for key people in case of absence.	NC
6	**PLANNING (ISO 9001:2015; Art.6.1,6.2, 6.3)**			
6.1	**Actions to Address Risks and Opportunities**			
6.1.1	**Determining Risks and Opportunities**			
a)	Are techniques / methods used to identify risks and opportunities?	*Different techniques:* *1) PFMEA, RPN value.* *2) SWOT (strengths, weaknesses, opportunities, and threats). 3) etc.....*	Yes, the factory applies PFMEA as a technique to identify risk and opportunities of improvement.	C
b)	Are risks and opportunities categorized per their severity of their impact?		Yes, the factory defined range (1 to 10) to assess level of Severity (S), Occurancy (O), and Detectability (D). Each risk identified will have a number 1 to 10. A value for RPN = Severity * Occurancy * Detectability is calculated for each risk which determines the impact of a risk.	C
c)	Has the organization considered risks from internal and external issues (4.1) they face which are relevant of interested parties (4.2)?	*1) Risk and opportunities introduced by **external issue** such as:* *Legal, Technological, Competitive, Market, Cultural, Social, Economic environments. 2) Risk and opportunities introduced by **Internal issues** such a s Organizational values, culture, Knowledge, and performance*	Yes, risk and opportunities introduced by external and internal issues were considered to give assurance that the QMS can achieve intended results.	C
d)	Is there an established plan/method detailing the actions to be taken to address risks and opportunities?	*Actions may include:* *- avoiding the risk* *- taking the risk in order to pursue an opportunity* *- sharing the risk* *- retaining the risk by informed decision*	Yes, a corrective action plan that contains solutions to address risk and opportunities is documented, with responsibility and completion date. They use RPN = Severity * Occurancy * Detectability > 100 as a limit to consider an issue a risk and opportunity for improvement.	C
e)	Is there evidence that consideration of risk and opportunities from internal and external issues (4.1) has been integrated in the QMS?	*Identify in which document solutions have been integrated.*	QMS documentation	C

PROQC INTERNATIONAL	ISO 9001:2015 Quality System Audit	Rev.
	AUDIT CHECKLIST	13

Supplier Name	Audit Date	Report No.
XXXXXXXXXXXXXXXXXXX	XXXXXXXXXXXX	XXXXXXXXXXX

C = Complies with the requirements, I = Improvement Needed, NC = Not Complies, N/A = Not Applicable

	QUESTIONNAIRE	EVIDENCE	FINDINGS	SCORE
f)	Are the actions adequate? Can actions appropriately assess the compliance of the risks and opportunities?	*1) Report of last internal / external audit. 2) Feedback from interested parties. 3) Evidence of continual improvement*	Up-to-date, around 45% of issues with RPN > 100 are implemented, with evidence visible. Up until now, the factory has not registered any compliants from interested parties.	C
6.2	**Quality Objectives and Planning to Achieve Them**			
a)	Are the Organization Quality Goals & Objectives documented? Are Quality Objectives measurable and consistent with the quality policy?	***1)** If any, **Take photo** of documented Quality Objectives.* ***2)** Check if Quality Objectives is been distributed to relevant departments / responsibilities in terms of metricable values.*	No quality metrics, KPIs are not defined for each process.	NC
b)	Are quality objectives communicated in any sort of media/form?		No quality metrics, KPIs are not defined for each process.	NC
c)	Has the Organization defined a plan or strategy to meet the Quality Goals and Objectives?	***1)** Ask Managers / Supervisors to explain their Quality Objectives.* ***2)** Ask them to show the methods / procedure they use to meet these objectives.*	Yes, strategy to meet the Quality Goals and Objectivesare defined in form of procedures and documented information	C
d)	Are Quality Objectives monitored and reviewed at reasonable intervals? (Take photo of the result).	***1)** Check if the review interval of Quality Objectives is defined in doc.* ***2)** Check the current result / trend of the last review, and **take photo**.* ***3)** Check if the result of monitoring are posted at a public board for employees to view. **Take photo***	No record of monitoring	NC
6.3	**The Planning of Changes**			
a)	Has the organization identified and documented potential changes?	*Potential changes may be: - In manufacturing process. - Raw material suppliers. - Legal requirements - Manufacturing center ...etc.*	Yes, there is a procedure)QMX-QP-12, Rev. A/O) in which the factory defines potential changes that may occur.	C
b)	Is the purpose of changes defined?	*Provide an example if any, including details of the purpose.*	Yes, for example, the factory implemented a change for purchasing raw materials instead of outsourcing this process; this is due to a reduced time for processing.	C
c)	Are potential consequences / risks documented and analyzed prior to applying the changes?	*For example, the consequence could be higher prices of purchased raw material (a risk that needs to be addressed)*	Yes, the risk of this change is higher prices of purchased raw material as a consequence, and the risk of using NCF raw material due to lack of incoming inspection.	C
d)	Is there a prevision / plan of how to implement changes to ensure the integrity of the QMS	*Example plan to ensure integrity of QMS*	Yes, selection of qualified supplier of raw material. Implementation of incoming inspection, ensure back-up material to avoid affecting customer satisfaction in quality and on-time delivery.	C
e)	Are resource available to implement the change?	*Identify the resources required to put the plan into effect, and assign those resources.*	New purchasing Manager, new QC to conduct incoming inspection.	C
f)	Are changes communicated to relevant people? changed responsibilities	*For example, who will be the person in charge of purchasing ?*	Yes, training was conducted, and records are available.	C
7	**SUPPORT (ISO 9001:2015; art. 7.1,7.2,7.3,7.4,7.5)**			
7.1	**Resources**			
a)	Has the organization determined and provided persons / responsible necessary for the establishment, maintenance and continual improvement of the QMS (7.1.1)?	*1) Check if there is a process for that. 2) Check and record who the process owner is. 3) Ask to see his Job description.*	Yes, there is a process for establishment and maintenance of QMS, under the responsibility of the QA department of 4 people lead by the Quality Manager, who also acts as Management Rep.	C
b)	Has the organization determined and provided persons responsible for the effective implementation of its QMS (7.1.2)?	*Check if each process is defined and provide: - Who does what. - Labor contracts. - Training records.*	Yes, each process has a process owner and a team of people to run the process. People working in each process are full-time employees with conform labor contracts.	C

PROQC INTERNATIONAL	ISO 9001:2015 Quality System Audit	Rev.
	AUDIT CHECKLIST	13

Supplier Name	Audit Date	Report No.
XXXXXXXXXXXXXXXXXXX	XXXXXXXXXXXX	XXXXXXXXXXX

C = Complies with the requirements, I = Improvement Needed, NC = Not Complies, N/A = Not Applicable

	QUESTIONNAIRE	EVIDENCE	FINDINGS	SCORE
c)	Has the organization determined, provided and maintained infrastructure for the operation of its processes to achieve conformity of product and services (7.1.3)?	*1) Number of buildings, and surfaces? 2) List of equipment, software, hardware. 3) Equip. for transportation. 4) Maintenance program / records. 5) Means of communication (Email, fax ..etc.)*	Yes, building and necessary facilities are provided both for production and living. Production equipment are well protected against weather, and maintained following a maintenance program. The record of maintenance is posted on each machine. The factory has an IT department to develop an email communication system.	C
d)	Has the organization determined, provided and maintained the environment necessary for the operation of its processes and to achieve conformity of products and services (7.1.4)?	*1) Cleaning schedule / cleanliness 2) Temperature, humidity control, devices. 3) Noise limitation and control. 4) Lighting system. 5) Safety, healthy ...etc.*	It was noted that employees work in a workshop that rejects noise high than acceptable standards, and ear plugs are not provided.	I
e)	Has the organization determined and provided resources for monitoring and measuring of conformity of products and services (7.1.5)?	*1) List of inspection / test instruments. 2) Calibration plan. 3) Photograph calibration status or tags. 4) Calibration cert. traceable to 3rd party national institute. 5) Condition of storage or retention.*	Yes, there is a list of inspection / test instruments, combined with the calibration plan. Each piece of equipment is calibrated by a 3rd party, and has a certificate. However, it was discovered that a few instruments did not have a calibration tag to indicate expiration date (See photo).	I
f)	When addressing changing needs and trends, has the organization considered its current knowledge and determined how to acquire or access any necessary additional knowledge and required updates (7.1.6)?	*Knowledge may include: 1) Learning from failure/customer feedback. 2) Experience. 3) Attending seminars, conferences, academia. 4) Obtaining international Standards.*	The organization has not defined means of collecting knowledge.	NC
7.2	**Competence**			
a)	Is adequate Manpower provided for quality activities?	***1)****Record of competence evaluation. 2) Skill matrix. 3) Work experience / CV. 4) Educational history.*	Yes, the factory has skill matrix which defines the level of competence of employees, based on CVs, work experience and school education.	C
b)	Has the Organization identified training needs and developed a documented training plan?	***1)*** *If any, **Take photo** of the training plan.* ***2)*** *Check if the training program includes training topics, trainer / trainee, date, evaluation method…etc.*	Yes, a training program has been documented with 24 training sessions in the year 2017. And it defines training topics, trainer / trainee and evaluation date.	C
c)	Are individual training records well established and	*1) If any, **Take photo** of a few training records selected from the program.*	Yes, training records are available. For example of the training conducted in IPQC for 4 QC people on 2017-03-12 (See photo).	C
d)	Has the effectiveness of training been evaluated through any type of examination or test?	*1) If any, **Take photo** of few evaluation records*	Yes, records of evaluation after the training are available. Examinations were conducted for only 2 QCs, did not see for others 2 QCs.	I
7.3	**Awareness**			
a)	Does employee training include the quality policy and the methods established to comply with it?	*1) Review employee training plan. 2) Evaluation of awareness*	Yes, a training program has been documented with 24 training sesions in the year 2017. It defines training topics, trainer / trainee and evaluation date. No record of evaluation of awareness.	I
b)	Are employees aware of quality objectives and issues that may affect the ability to meet them?	*1) Interview workers. 2) Quality objectives posted*	It was noted that quality objectives are posted in the workshop. But 60% of interviewed people were not aware of their objectives.	I
c)	Are employees informed about their direct contribution and benefit to meeting quality objectives?	*1) Interview workers to see if they are aware of their role and contribution.*	Yes, 80% of interviewed people know the direct contribution of their role.	C
d)	Are employees aware of the impact of nonconformance?	*1) Interview workers to see if they are knowledgeable of the benefits the organization obtains from performing well as a whole.*	Yes, 80% of interviewed people know the direct contribution of their role.	C
7.4	**Communication**			
a)	Is critical information identified to be shared internally?	*1) Ex. - Quality Performance - Technology updates - New client requirements*	Yes, there is a procedure (QP-23, Rev 4) that defines what type of information to share internally, who shares it and how.	C
b)	Is critical information identified to be shared externally?	*1) Ex. - Business performance - Client satisfaction - Performance reviews - Policy updates*	Yes, there is a procedure (QP-23, Rev 4) that define what type of information to share externally, who shares it and how.	C

PROQC INTERNATIONAL	ISO 9001:2015 Quality System Audit	Rev.
	AUDIT CHECKLIST	13

Supplier Name	Audit Date	Report No.
XXXXXXXXXXXXXXXXXXX	XXXXXXXXXXXX	XXXXXXXXXXX

C = Complies with the requirements, I = Improvement Needed, NC = Not Complies, N/A = Not Applicable

	QUESTIONNAIRE	EVIDENCE	FINDINGS	SCORE
c)	Is information communicated in a timely manner?	*1) Ex. monthly, quarterly, yearly*	No, it was noted that KPIs are supposed to be posted monthly, but it were not posted in the last couple of months.	NC
d)	Has the organization identified all the internal interested parties to whom information will communicated to?	*1) Ex.* *- By departments* *- Specific employees*	Yes, there is a procedure (QP-23, Rev 4) that defines what type of information to share internally, who shares it and how.	C
e)	Does the organization identify all the external interested parties to whom information will communicated to?	*1) Ex.* *- Clients* *- Stakeholders* *- Suppliers* *- Business partners*	Yes, there is a procedure (QP-23, Rev 4) that defines what type of information to share externally, who shares it and how.	C
f)	Is there an established method to communicate information relevant to quality management system?	*1) Ex:* *-Newsletter* *- Official Statements* *- Email*	Yes, there is a procedure (QP-23, Rev 4) that defines what type of information to share internally, who shares it and how.	C
g)	Has the organization nominated a person/department in charge of communicating information internally and externally?	*Who share information at internal?* *Who share information at external?*	Yes, The Quality Department Manager is in charge of providing information about KPIs internally and externally.	C
7.5	**Documented Information**			
7.5.2	**Creating and Updating**			
a)	Are quality system procedures & work instructions documented and identified?	***1)*** *Check if each document is identifiable with doc. Number / Rev. date, author ..etc. .* ***2)*** *Photograph an example of document identified.*	Yes, each procedure and work instruction is well identified with Doc#, Rev#, Author, and publication date. Example of procedure QP-021, Rev A/0, and Template of IQPC, Sheet QP-021-02, Rev 1 that they use to record document changes.	C
b)	Is there a **documented procedure** in place that describes approval, distribution and change control for internal documents.	***1)*** *Write doc # and Rev. #.* ***2)*** *Ask the audited person to describe the process and cross check if it matches with the procedure.*	Yes, example of procedure QP-021, Rev A/0.	C
c)	Is there evidence that approval, distribution and change of documents are properly followed as described in the procedure?	***1) Photograph record*** *of distribution.* ***2)****Check if the distribution list includes Doc #, Rev, distribution date and signature of the user.*	Yes, a distribution record is maintained in sheet QP-001-01, with a list of document distributed, Rev. distributed and signature of the user who received the copy (See photo).	C
d)	Is any form of media (**Paper, electronical**) used as a method to document procedures / work instructions?		Yes, all procedures and work instructions are in paper form, including some sheets.	C
e)	Is there is a **master list** of all controlled documents that includes current revision and distribution information	*Photograph the master list of documents*	Yes, a masterlist if available (See photo) in the sheet QP-001-01	C
f)	Is a documented procedure in place that describes control for **external documents** and is there evidence that it is being followed.	***1)*** *Write doc # and rev. #* ***2)*** *If any,* ***Take photo*** *of the masterlist containing external documents.*	Yes, example of procedure QP-021, Rev A/0. a masterlist with external documents recorded.	C
7.5.3	**Control of Documented Information**			
a)	**Is appropriate documented information** available at all locations where they are used.	***1)*** *Select 3 major documents from the distribution list, and cross check if the user on site has same revision document (Quality Department for example).* ***2)*** *Note the doc#/ Rev.# of document verified.*	Yes, the auditor selected 3 documents from the masterlist with the following document number: QP-011, Rev A/1, QP-004, Rev A/2 and QP-004-02. A copy of these documents are provided to the Production department, and they were found available in place with the same revision number.	C
b)	Are Procedures in place defining the **type**, **location**, **protection, retrieval**, **retention period** and **disposal** of documented information?	*1) Write doc # of that procedure.* *2) Photograph masterlist of document.* *3) Photograph masterlist of records.*	Yes, example of procedure QP-021, Rev A/0.	C
c)	In which **location** is documented information stored, are there easy to find?	*Location is protected against loss or destruction.*	All master documents are stored in the office of the Quality Department, in a locked cupboard.	C
d)	**Are changes to the documented information** reviewed and approved by an individual in the same function or organization that performed the original review and approval.	*1) Guidelines in the procedure.* *2) Signature of an authority .* *3) Authority is the same person or function that approved the original / previous revision.*	Yes, as is required in procedure QP-021, Rev A/0, paragraph 4, all procedures, WIs must be reviewed and approved by respective responsible person.	C

PROQC INTERNATIONAL	ISO 9001:2015 Quality System Audit	Rev.
	AUDIT CHECKLIST	13

Supplier Name	Audit Date	Report No.
XXXXXXXXXXXXXXXXXXX	XXXXXXXXXXXX	XXXXXXXXXXX

C = Complies with the requirements, I = Improvement Needed, NC = Not Complies, N/A = Not Applicable

	QUESTIONNAIRE	EVIDENCE	FINDINGS	SCORE
e)	Are approved changes communicated to the appropriate personnel in a **timely** manner.	***1)*** *Signature of the user in document*	Yes, approved changes are distributed, and record of distribution maintained in the sheet QP-001-01	C
f)	Is the **retention period** of each record defined in the procedure?	*Is the retention period defined according to the expected life of the product but not less than 2 years from date of distribution?*	Yes, there is a list of records to retain, and each has a retention period of at least 2 years	C
g)	Are records that are required to be destroyed after a period of time identified?	***1)*** *Check if there any specific identification such as "DESTROY" assigned to such record.* ***2)*** ***take photo*** *if such record available.*	No, there is no specific identification used for documented information that has passed the retention period.	I
8	**OPERATION (ISO 9001:2015; Clause. 8.1, 8.2, 8.3, 8.3, 8.4, 8.5, 8.6, 8.7)**			
8.1	**Operational Planning and Control**			
a)	Has the organization planned a process for operation?	*1) Product / service requirement (Inputs)* *2) Criteria to controls process* *3) Procedures / WI for inspection, test, verify.* *4) Machines, equip.* *5) Man power*	Yes, there is a process for Operation.	C
b)	Has the organization identified risks and opportunities on operational processes (using risk-based thinking)?	*1) Risks and Opportunities.* *2) Plan to mitigate risk*	No, risk and opportunities are not identified	I
c)	Is the plan for the control of this process?	*1) Quality metrics*	Not defined	I
8.2	**Requirements for products and services (Inputs)**			
8.2.1	**Customer Communication**			
a)	Is there a plan to communicate with customers in timely manner about products and services?	*1) Review customer service procedures.*	Yes, stages for communication are defined in the process.	C
b)	Does the order review identify the risk of not making on-time deliveries, and include action to eliminate the risk?	***1) Photograph records*** *of orders review, not POs number reviewed.*	Yes, the order review No. 271 conducted in Jan 27 identified lack of personnel to finish the production in the time required by the client. The solution adopted was to sub-contract part of production.	C
c)	Has the organization established contingency actions in case something goes wrong?	*1) Review the potential issue and plan*	Yes, a contingency action is documented in procedure QP-015, Rev A/0.	C
8.2.2	**Determining the requirements for products and services**			
a)	Is there an authority to determine customer requirements before launching product development or production?	***1)*** *Check the job description.* ***2)*** *Signature of that authority on related records.*	Yes, Account Manager acting as customer rep. is assigned to determine customer requirements, See Organizational chart.	C
b)	Due to the nature of your product, are there "other" standards such as BS EN…, or ISO, not stated by the customer, but to which this product should adhere?	***1)*** *If any, note the code number, and current revision level of the standard applied to the 2 products selected.*	Yes, industrial standards related to products are defined in the requirements / drawings.	C
c)	Due to the nature of your product, are there statutory and regulation requirements determinate for health and safety of users, and for environmental protection?	***1)*** *If any, note the code number, and current revision level of the standard applied to the 2 products selected.*	No statute and regulations defined, not applicable	N/A
8.2.3	**Review of the requirements for products and services**			
a)	Is there an authority to review requirements for products and services?	***1)*** *Photograph the record of review with signature of authorities on related records.*	Yes, a cross functional team including the Quality, Production, Purchasing department and Lab will review requirements.	C
b)	Is there a procedure/system for order review before development or production?	***1) Photograph records*** *of order review, note PO number reviewed.*	Yes, there is process for order review.	C
c)	Is there procedure/system for monitoring of order changes?	***1) Photograph records*** *of order review, note PO number reviewed.*	Yes, it is included in the process.	C
8.2.4	**Changes to requirements for products and services**			
a)	Does the order review procedure define how **order changes** are processed / approved? Is there evidence of proper implementation.	***1) Photograph records*** *of orders review, note POs number reviewed.*	Yes, it is defined	C
b)	Is there a procedure established to notify relevant personnel of any changes applied to products and services?	*1) Write Doc #, Rev # and section / paragraph of where it's written.*	Yes, it is defined in the process	C

PROQC INTERNATIONAL	ISO 9001:2015 Quality System Audit	Rev.
	AUDIT CHECKLIST	13

Supplier Name	Audit Date	Report No.
XXXXXXXXXXXXXXXXXXX	XXXXXXXXXXXX	XXXXXXXXXXX

C = Complies with the requirements, I = Improvement Needed, NC = Not Complies, N/A = Not Applicable

	QUESTIONNAIRE	EVIDENCE	FINDINGS	SCORE
8.3	**Design and Development of Products and Services**			
8.3.2	**Design and development planning**			
a)	Is there a process for establishment, implementation and maintenance of Design and Development activities?	*1) Product / service requirement (Inputs)* *2) Criteria to controls process* *3) Procedures / WI for inspection, test, verify.* *4) Machines, equip.* *5) Man power*	Yes, there is a process documented in process map as COPs, and it is defined in procedure QP-08, Rev. A/0.	**C**
c)	Does the organization determined the nature, duration and complexity of design and development?	***1)*** *Write doc # and current revision level.*	Yes, it is defined for each new project.	**C**
d)	Are responsibilities and authorities defined for the design and development process?	***1)*** *Review record of design & development. Note the individual (s) responsible.*	Yes, responsibilities and authorities are defined in sheet QP-08-02 for each new project.	**C**
e)	Is there a **Plan for Design & Development?** Is there evidence of implementation?	*1) Photograph a gnatt chart .* *2) Check if timeline is clearly defined.*	Yes, there is a gnatt chart for each project, with defined steps. Each step has a deadline and resp.	**C**
k)	Is the **Design & Development transfer stage** planned?	***1)*** *Write the doc #, and Rev. #*	Yes, the step for transfer is planned at the end.	**C**
l)	Is the method for the control of **Design & Development change** throughout the product design and life cycle defined in the procedure?	***1)*** *Write the doc #, and Rev#, section.*	Yes, the method to implement changes during design and dev. process is planned in procedure QP-08.	**C**
8.3.3	**Design and Development inputs**			
a)	Has the organization determined functional and performance requirements for the specific types of products and services to be designed and developed?	*1) Photograph record of inputs*	Yes, functional and performance requirements are identified from client's requirements and recorded on sheet QP-08-03.	**C**
b)	Are potential consequences of failure due to the nature of the products and services identified and documented?	*1) Review record.*	Yes, failures are identified from previous experience.	**C**
8.3.4	**Design and development controls**			
a)	Are results to be achieve are clearly defined?	***1)*** *Write doc # and current revision level.*	Yes, planned result to achieve are defined and documented in sheet of Verification and validation	**C**
b)	Doess the Design & Development include the requirement to conduct **Reviews at various stages?**	***1)*** *Write the doc #, and Rev#, including paragraph.* ***2)*** *Write stages of design & Development.*	Yes, review stages are planned in the gnatt chart of audited project #. HM-0234	**C**
c)	Are activities for **verification** defined in the Design Plan?	***1)*** *Write the doc #, and Rev#, including section where detail of verification method are listed.* ***2)*** *Photograph record of verification conducted in same product .*	Yes, activities for verification are planned for project HM-0234, to check actual output correspond to requirements in the product drawing. The result of verification is documented in sheet Q-023, and signed by appropriate authority	**C**
d)	Are activities for **Validation** defined and performed per the plan and documented?	***1) Photograph*** *of record of validation conducted in same product, and check records are signed by assigned authority.*	Yes, activities for validation are planned for project HM-0234, to check actual performance in field meet requirements. The validation is done at client side, and result documented in sheet Q-0234, and signed by appropriate authority	**C**
e)	Has the organization taken necessary actions on problems, if any, as determined during the reviews, or verification and validation activities?	*1) record of CA*	Yes, corrective action to solve NCF found during verification or / and validation are planned if necessary.	**C**
8.3.5	**Design and development outputs**			
a)	Do design and development outputs meet requirements of inputs?	***1) Photograph*** *record of Design outputs for any product.*	Yes, design and development outputs can meet requirements of inputs, they are recorded on sheet QR-012	**C**
b)	Do outputs include or reference monitoring and measuring methods, and acceptance criteria, as applicable?	*1) Work Instruction*	Yes, they include methods for monitoring and measuring, and also acceptance criteria.	**C**

PROQC INTERNATIONAL	ISO 9001:2015 Quality System Audit	Rev.
	AUDIT CHECKLIST	13

Supplier Name	Audit Date	Report No.
XXXXXXXXXXXXXXXXXXX	XXXXXXXXXXXX	XXXXXXXXXXX

C = Complies with the requirements, I = Improvement Needed, NC = Not Complies, N/A = Not Applicable

	QUESTIONNAIRE	EVIDENCE	FINDINGS	SCORE
c)	Are significant characteristics of the products / services properly specified.		Yes, significant product characteristics are identified in drawing.	C
8.3.6	**Design and development changes**			
a)	Are design and development changes documented and maintained?	*1) Review 2 examples if any.*	Yes, planning for changes that could happen during design phase, or before production are defined, including their identification, implementation and monitoring. However, changes have never been requested, so there are no records.	N/A
b)	If any, are results of changes reviewed prior to approval?		No record since changes have never happened at those stages.	N/A
c)	Is there an established authority to authorize changes to design & development? Has the authority review whether outputs meet the changes applied?	*1) Review documents are signed by proper authority.*	Yes, authorities for implementation of changes are the same as those in charge of the design and dev. Process.	C
d)	Has the organization taken necessary actions on problems, if any, determined during the reviews, or verification and validation activities after changes have been applied?	*1) Review assessment of impacts*	No record since changes have never happened at those stages, so no records of further action.	N/A
8.4	**Control of externally provided processes, products, and services**			
8.4.1	**General**			
a)	Is there a masterlist of all external service providers?	***1) Review list.***	Yes, the factory maintain a masterlist of qualified services providers on sheet QR-84.	C
8.4.2	**Type and extent of control**			
a)	Is there a documented procedure that defines the type of controls being applied to external service providers.	***1)*** *Write doc #, and Rev.#*	Yes, there is a procedure QP-12, Rev A/0 as a guideline for control of service providers.	C
b)	Is there a procedure defining methods to monitor external services or product providers?	***1)*** *Write doc #, and Rev.#* ***2)*** *Photograph records conformity rate, On time delivery rate..etc.. as supplier performance evaluation.*	Yes, there is a procedure QP-12, Rev A/0 as a guideline for controls of service providers. Records of performance are not visible.	I
c)	Is there a reaction plan when an external service or product provider has poor performance? Are performance data relating to supplier performance communicated to supplier?	***1)*** *Write doc #, and Rev.# of where reaction plan are defined.* ***2)*** *Check if there records of such reaction.*	No reaction plan, it was found that the factory rejected lot #. 2031 from raw material supplier XXCXX, but no information recorded, no action plan for that supplier.	NC
8.4.3	**Information for external providers**			
a)	Is there a documented procedure defining external service or product provider evaluation and approval, including acceptance requirements / criteria.	***1)*** *Write doc # and rev. #* ***3)*** *Photograph evaluation report for 3 main suppliers.*	Yes, there is a procedure QP-023, Rev A/0. Records are available.	C
b)	Is there a written agreement / contract with external service or product provider?	*1) Review contracts.* *2) Take photo if any*	Yes, there are quality agreements signed.	C
c)	Is there a procedure defining method and time period for sharing results from the performance assessment with an external provider?	***1)*** *Write doc #, and Rev.#* *2) Record method and time period for 2 largest external providers.*	Yes, performance is communicated to external provider.	C
8.5	**Production and service provision**			
8.5.1	**Control of production and service provision**			
a)	Does the organization identify, document and control all operation processes?	*1) Review operation flow chart*	Yes, there is a production flow chart documented that describes all steps of realization of products.	C
b)	Are monitoring and measuring resources available and suitable for the control of production and service provision?		Yes, resources are available and suitable for the product to be made.	C
c)	Are Work Instructions (eg. setting up a machine, performing an inspection, packaging a product, etc.) identified in a flow chart and readily available to operators?	*1) Review working instructions*	Yes, Work Instructions are posted on site	C

PROQC INTERNATIONAL	ISO 9001:2015 Quality System Audit	Rev.
	AUDIT CHECKLIST	13

Supplier Name	Audit Date	Report No.
XXXXXXXXXXXXXXXXXXX	XXXXXXXXXXXX	XXXXXXXXXXX

C = Complies with the requirements, I = Improvement Needed, NC = Not Complies, N/A = Not Applicable

	QUESTIONNAIRE	EVIDENCE	FINDINGS	SCORE
d)	Are performance indicators to measure the effectiveness of operation processes available and controlled? Does the organization keep records?	*1) Review type of performance indicator.* *2) Take photo of records*	Yes, KPIs are defined, such as defect rate, on time delivery, and graphics are posted on site.	**C**
e)	Has the organization established a procedure for actions to be taken to prevent human error from affecting the quality system?	***1)** Write the doc #, and Rev. #* *2) Include photo of actions to be taken to prevent human error/*	Yes, action in the form of poka-yoke are established on site to prevent human error, see photo.	**C**
8.5.2	**Identification and traceability**			
a)	Are there procedures that define the identification of product and materials at various places, and is there evidence of compliance?	***1)** Identification In receiving.* *2) Identification In production area.* *3) Identification In warehouse.* .	Yes, there is procedure QP-8.5, Rev A/0. Raw materials are identified with lot numbers. Products in workshop are identified with process cards, on which part number and date is written.	**C**
d)	Is there a procedure / system that describes how product tracking data is to be captured, and is there evidence of compliance?	*1) Write doc.# / Rev.# where those requirements are detailed.* *2) Check if the factory uses an IT program such as an ERP system or any manual system to capture and maintain product tracking data for traceability.*	PO number is used to track production data. Data are incorporated in the ERP system	**C**
8.5.3	**Customer or external provider property**			
a)	Is there a procedure in place that specifies methods of handling customer or external provider property to avoid damage, deterioration, contamination, or other adverse effects.	*1) Write doc.# / Rev.# where those requirements are detailed.*	Yes, there is a procedure QMX-QP-14, Rev A/O as a guideline for handling customer property.	**C**
b)	Are customers or external providers property such as machines, tool, samples, drawing..etc.. identified with the name of the customer or external provider status?	*Take photo of customer properties if any*	Yes, the factory uses MOLDs as customer property. Each one is marked with a customer name (See photo).	**C**
8.5.4	**Preservation**			
a)	Are there procedures in place that specify material handling to and from stock locations to assure protection from mix-ups, damage, deterioration, contamination, or other adverse effects. And there is evidence of compliance.	***Check if** boxes or fixtures used to handle material are adequate to prevent damage, **take photos.***	Yes, there is a procedure (QP-8.54, Rev A/0) for preservation of material and products.	**C**
b)	Are procedures/practices in place for storage areas that prevent mix-ups, damage, deterioration or other adverse effects? Are areas neat and well organized?	***1) Take photo** of the storage condition in the warehouse or any allocated storage area.*	Yes, the factory has a warehouse, and materials are stored correctly to avoid deterioration, mix-up.	**C**
c)	Is a procedure in place to control materials with limited shelf life to prevent expiration or deterioration.	***1)** Likely, this question will mostly be apply for **batteries, chemical products, medicines**...etc. If any of these products are a concern, then check if storage life limit is defined, and what the reaction plan is after the period has expired. Otherwise, this question might not be applicable.*	No, the factory does not use batteries, or chemical products.	**N/A**
d)	Is there a procedure established that describes the methods for authorizing receipt from and dispatch to storage areas and stock rooms? And there is evidence of compliance?	***1)** Check if there is a responsible person in charge of IN/OUT check in the warehouse.* ***2)** Check if there are records of IN/OUT signed by that person, and a **take photo** of that record, if any.*	Yes, products arriving first are used fist. The date of arrival indicates that it must be used first. But there is a risk that they will use new material before old meterial.	**I**
8.5.5	**Post-delivery Activities**			
a)	Has the organization established a procedure to handle potential undesired consequences associated with products and services?	*1) Undesired consequences may include:* *- delayed shipment* *- damage of goods* *- release of non-conforming product* *- damage of packaging*	Yes, there is a procedure QMX-013, Rev A/0 as a reaction plan to handle undesired situations.	**C**
b)	If applicable, is intended lifetime of products and services documented by the organization?	*1) Review packaging tag*	No life time applied.	**N/A**
c)	If any, does the organization identify any packaging or delivery requirements from the customer?		Yes, organization identifies the packaging and delivery requirements from the customer.	**C**

Supplier Name	Audit Date	Report No.
XXXXXXXXXXXXXXXXXXX	XXXXXXXXXXXX	XXXXXXXXXXX

C = Complies with the requirements, I = Improvement Needed, NC = Not Complies, N/A = Not Applicable

	QUESTIONNAIRE	EVIDENCE	FINDINGS	SCORE
d)	Does the factory provide warranty provisions for unwanted potential damage goods may suffer post-delivery?	*1) Review warranty policy*	Yes, factory provide warranty provisions for unwanted potential damage goods may suffer post-delivery.	C
e)	Does the organization provide customer feedback for future improvement? If any, is negative feedback reviewed and properly assessed? Are records maintained?	*1)Review feedback records* *2) Take photo if any*	Yes, factory collects feedback as part of customer satisfaction surveys, and they use it as input for further improvement.	C
8.5.6	**Control of Changes**			
a)	Does the organization document, control, and maintain records of changes for production or service provision to ensure continuing conformity with requirements?	*1) Review records of change.* *2) Take photo if any*	Yes, there is a procedure QP-024, Rev A/0 as a guideline to handle changes within the organization, including the production process.	C
b)	Are changes reviewed and authorized by competent personnel?		Yes, records of changes must be reviewed and approved by an authorized person.	C
8.6	**Release of products and services**			
a)	Does the organization identify, monitor and measure product/service characteristics to verify conformity to requirements?	*1) Review records to monitor and measure characteristics.* *2) Product characteristics may be dimensional, functional, performance, reliability, durability, maintainability, life, cost.*	Yes, there are work instructions, for example of WI-QR-34, in which product characteristics are mentioned, including sample plan, and measuring method.	C
c)	Are all personnel, performing monitoring and measurement, trained and competent?	*1) If service is sub-contracted, review competence of sub-contractor.*	Yes, personnel are trained and training records are available.	C
d)	Is there written approval/waiver from a relevant internal authority or the customer prior to releasing the product?	*1) Review approval/waiver from relevant internal authority or customer*	Yes, there is written approval/waiver from the Quality Manager prior to releasing the product.	C
e)	Can authorization records for release of products or service be traced back to a person(s)?	*1) identify traceability of records.*	Yes, signature of the Quality Manager is visible on the record, as evidence.	C
8.7	**Control of nonconforming outputs**			
a)	Is there a procedure that defines the marking and identification of non-conforming material? Is there evidence of compliance?	***1)** Write doc #, and take photo of Non-conforming product identified if any*	Yes, there is a procedure QP-027, Rev A/0 that defines methods of handling NCF products / materials. Each material is identified, and placed in a red area or red boxes.	C
b)	Is there a procedure that requires evaluation of nonconformities, including documentation of any needed investigation. Is evidence of compliance available?	***1)** Write doc # of that procedure*	Yes, the procedure QP-027, Rev A/0 requires an evaluation of NCFs to confirm their status, and respective reaction to them.	C
c)	Is there a physical segregation of nonconforming material during subsequent storage & processing? And, is there evidence of compliance?	***1)** Check if that area is delimited with a clear red line in the floor, and with a visible label, or protected with a key to avoid unwanted mixing, **Take photo** of the area.* ***2)** Check red boxes are used to separate non-conforming products from good products, and **take photo.***	Yes, the factory separates defect by code and boxes. Specific areas painted in red are used to store products away from good one, to avoid mix-ups (SEE PHOTO).	C
d)	Is there a procedure that defines disposition options and conditions of non-conforming material (scrap, rework, return, use as is, deviate)? Is there evidence of compliance?	***1)** Write doc # of that procedure*	Yes, reaction plan when found NCF is scrap. Cannot be reworked.	C
e)	Is there a procedure that describes how re-work will be accomplished and documented and is there evidence of compliance?	***1)** Write doc # of that procedure.* ***2)** Check if there a list describing the content of the area, with part / lot number, date and a decision of what to do with those parts.*	Not applicable	N/A
9	**PERFORMANCE EVALUATION (ISO 9001:2015; art. 9.1, 9.2, 9.3)**			
9.1	**Monitoring, measurement, analysis, and evaluation**			
9.1.1	**General**			
a)	Does the organization determine what needs to be monitored and measured?	*1) It could include:* *- Quality Objectives & Goals* *- Performance indicators* *- Customer satisfaction*	No, each process does not have KPIs as plan for monitoring. No performance indicators, except for customer satisfaction survey.	I

PROQC INTERNATIONAL	ISO 9001:2015 Quality System Audit	Rev.
	AUDIT CHECKLIST	13

Supplier Name	Audit Date	Report No.
XXXXXXXXXXXXXXXXXXX	XXXXXXXXXXXX	XXXXXXXXXXX

C = Complies with the requirements, I = Improvement Needed, NC = Not Complies, N/A = Not Applicable

	QUESTIONNAIRE	EVIDENCE	FINDINGS	SCORE
b)	Have methods for monitoring, measuring, analyzing, and evaluating validity of results been defined and identified?	*1) Methods may include statistical performance.* *2) Data analyses processes methods and resources such as time, manpower, computer, software, statistical tools, etc.*	No methods for monitoring, measuring, analyzing, and evaluating results, except for customer satisfactory survey.	I
c)	Are methods describe how (manually, ERP system…etc.), when (Daily, monthly, quarterly…etc.) and who to monitor and measure Quality Goals & Objectives? Are there evidence of implementation?	***1)** Take photo if the plan if any* ***2)** Review record of monitoring and measurement, **take photo***	Not such plan of how, when and who to monitor and measure KPIs.	NC
9.1.2	**Customer Satisfaction**			
a)	Is there a procedure / system as a guideline to conduct customer satisfaction surveys?	*Write doc.# / Rev.#* *- Customer feedback (complaint). -* *Order and delivery performance*	Yes, there is a procedure for customer satisfaction surveys. They are conducted twice per year.	C
b)	Are customer satisfaction surveys conducted in periodical manner as required? How many times a year? Is there evidence of implementation?	*Review the records of customer satisfaction, and **take photo**, if any.*	Yes, twice a year. Each time, the factory will select typical customers for the survey, and collect actual feedback, survey questionnaire and internal performance. Records are available.	C
c)	Are there follow up actions for improvement after the survey?	***1)** Check if there is a Corrective Action Plan defining topics to improve, timeline and responsibility, **take photo,** if any.*	Yes, results of follow ups are documented, with an improvement action plan.	C
9.1.3	**Analysis and evaluation**			
b)	Is there a system / procedure for the collection of manufacturing performance (i.e., SPC, Internal PPM, defect rate)? Is there evidence of implementation?	***1)** Write doc # and Rev.# (Not mandatory)* ***2)** Review the summary of trends vs targets, **take photo,** if any.*	No specific plan for collection of results of KPIs since they are not defined, except for customer survey.	I
e)	Is there a system / procedure to evaluate the effectiveness of actions taken to address risks and opportunities?	***1)** Write doc # and Rev.# (Not mandatory)* ***2)** Review the summary of trends vs targets, **take photo,** if any.*	Yes, there is a procedure for identification and evaluation of effectiveness of risk and opportunities.	C
d)	Has the organization identified a need for improvements to the quality management system?	***1)** Write doc # and Rev.# (Not mandatory)* ***2)** Review the summary of trends vs targets, **take photo,** if any.*	Yes, it has identified such a need.	C
9.2	**Internal Audit**			
a)	Does the audit plan / scope address all areas covered by the quality systems & cover all requirements of regulations?	***1)** Review the audit checklist used and its record.*	Yes, there is an audit plan documented in sheet QR-010, with a scope covering all areas of applicable ISO 9001 clauses.	C
b)	Is there a documented procedure controlling internal audits? Does the audit procedure contain a provision for re-audits if non-conformities are found?	*1) Write doc #, and Rev. # , including the paragraph for the previsions of re-audits.*	Yes, there is a procedure (QP-010, Rev A/0) for conducting a internal audit, including the prevision for re-audits in clause 4.5	C
c)	Have Quality system audits been scheduled & completed and are audit documents on file?	*1) Review the last 2 consecutive audits planned, Take a photo of the last audit plan, and write the audit dates.*	Yes, the last 2 internal audits were conducted in 2016-06-12 and 2016-12-23. Result of the audits were published with 11 NCFs found in the 1st audit, and 8 in the 2nd audit.	C
d)	Are Internal auditors trained and are they independent of the areas audited?	***1)** Review certificate / training & qualification records of Auditors assigned. **Take photo** of the Auditors certificates, if any.* ***2)** Review if any and Auditor was scheduled to audit his own department, **take photo** of the Auditors scheduling.*	Yes, the factory has 4 auditors certified by TUV, Certificates are available in HR (See photo). They were scheduled independently.	C
e)	Are any audit findings properly documented and is there evidence of actions taken?	***1)** Check if there is a specific form used to record NCFs and corrective action.* ***2)** Check if all NCFs are closed, and the signature of the Auditor who found the NCF is the same as the one verifying the effectiveness of the correction of that NCF. **Take photo,** of a NCF.*	Yes, audit findings are recorded on sheet QR-010-2 (See photo). As for the last audit of 2016-12-23, it was discovered that 7 NCFs were closed, but only 4 of them had the signature of the auditor as evidence of verification.	I
9.3	**Management Review**			
9.3.1	**General**			
a)	Is there a documented management review procedure / system and is it under revision control.	*1) Write the doc# and Rev.#.*	Yes, there is procedure QP-016, Rev A/0 as a guideline for conducting management reviews. They are conducted once per year.	C
9.3.2	**Management review inputs**			

PROQC INTERNATIONAL	ISO 9001:2015 Quality System Audit	Rev.
	AUDIT CHECKLIST	13

Supplier Name	Audit Date	Report No.
XXXXXXXXXXXXXXXXXXX	XXXXXXXXXXXX	XXXXXXXXXXX

C = Complies with the requirements, I = Improvement Needed, NC = Not Complies, N/A = Not Applicable

	QUESTIONNAIRE	EVIDENCE	FINDINGS	SCORE
a)	Are plans to collect inputs and related analysis of actual situations defined in the procedure?	***1)*** *Results of audits and their analysis.* ***2)*** *Customer feedback and their analysis* *3) Processes performance and their analysis.* *4) Status of preventive & corrective actions.* *5) Follow-up of previous reviews.* *6) Changes that could affect the QMS.* *7) Recommendation for improvements*	Yes, the procedure QP-016, Rev A/0 has a plan to collect those records as inputs for the management review.	C
b)	Is there clear indication of which department / personnel shall be responsible for providing inputs?	*1) Check if name of personnel / signature are visible in respective inputs reports.*	Yes, responsibilities for providing inputs are defined.	C
c)	When was the most recent management review conducted?	***1)*** *Write the date of the 2 last reviews.* ***2)*** *Review the record of inputs / outputs of both review.*	The last management review was conducted on 2017-1-21. Records of in/outputs are available, including attendance, on sheet QR-16-01.	C
9.3.3	**Management review outputs**			
a)	If applicable, do the management review outputs include decisions and action taken related to opportunities of improvement, changes needed, and/or resource needs?	*1) Document outputs from the last ONE reviews.*	Yes, the record of output is documented in sheet QR-016-03 for the last management review conducted in 2017-1-21.	C
10	**IMPROVEMENT (ISO 9001:2015; art. 10.1, 10.2, 10.3)**			
10.1	**General**			
a)	Is there a system / procedure as a guideline for identification of opportunities for improvement?	*1) Write doc # and its revision #.*	Yes, there is a procedure QP-021, Rev A/0 as a guideline for identification of opportunities for improvement, and their implementation.	C
b)	Is there a responsible person in charge to conduct this identification? What tool is used to conduct such identification?	*1) Check if any or multiple of the following techniques are used: Internal Audit, PFMEA, process capability, SPC, data analysis…etc.*	Yes, The Quality Manager leads the implementation of the procedure QP-021. They use PFMEA as a basic tool for identification and selection of opportunity for improvement.	C
c)	Is there any list of opportunity for improvement approved, budget, timeline of implementation? Is evidence and the result of such improvement visible?	*1) Take photo of the list.* *2) And explain the status (Before / After)*	Yes, they created a list of opportunities in sheet QR-021-01 which has 4 opportunities identified, with an implementation budget and goal. It has not yet been approved by top management.	C
10.2	**Nonconformity and corrective action**			
a)	Are procedures defined as guidelines to capture any complaint, conduct investigation of root causes of nonconformities and to define appropriate corrective Action to prevent re-occurrence?	***1)*** *Write doc # and its revision #.* *2) Check if there is an authority who received the complaint and communicated it to internal people.*	Yes, there is a procedure to capture complaints, and initiate investigation of root cause QP-024, Rev A/0. The Sales Manager acting as customer rep is in charge of capturing the client complaint. The Quality Manager is in charge of initiating investigation of the root cause, and implementing a CAP.	C
b)	Does the factory maintain a list of complaints (Internal / External)? Is there evidence that those complaints are **analyzed** to identify root causes and opportunities to implement corrective actions?	***1)*** *Check if there is a list of complaints, describing well the complaint issue, Part / Lot number, quantity, date, and target closing date. And write number of complaint if any* ***take photo****.*	Yes, the factory maintain a list of customer complaint, 12 complaints were collected in the year 2017, with all details.	C
c)	Is there a template/form to document the **decision making process** to pursue investigation and root cause corrective action?	***1)*** *Write doc #,* ***Take photo*** *of the form used*	Yes, the factory use an 8D report template QR-024-01.	C
d)	Is there evidence that the **corrective action** has been fully documented?	***1)*** *Select 2 complaints from the complaint list,* ***take photo*** *of 8D report or any record that shows the investigation and corrective action to fix the problem.* ***2)*** *Check if the CAPA describes clearly how to correct the issue to prevent reoccurence, and how to detect reoccurence.*	Yes, reviewed complaint received on Jan 21 and March 10th, on product number GH-210 and GH-52 respectively. Root causes were investigated, and corrective action implemented.	C
e)	Is there evidence that the **preventive action** has been fully documented? .	***1)*** *Select 2 complaints from the complaint list, and check if it describes clearly how to prevent reoccurrence of the same issue.*	Yes, reviewed complaint received on Jan 21 and March 10th, on product number GH-210 and GH-52 respectively. Root causes were investigated, and corrective action implemented.	C

PROQC INTERNATIONAL	ISO 9001:2015 Quality System Audit	Rev.
	AUDIT CHECKLIST	13

Supplier Name	Audit Date	Report No.
XXXXXXXXXXXXXXXXXXX	XXXXXXXXXXXX	XXXXXXXXXXX

C = Complies with the requirements, I = Improvement Needed, NC = Not Complies, N/A = Not Applicable

	QUESTIONNAIRE	EVIDENCE	FINDINGS	SCORE
f)	Are effectiveness of any corrective actions taken verified?	***Any proof that it is effective.***	Records in the 8D report demonstrate that verification was conducted. However, since they have never produced the products, GH-52 and GH-210, the impact of the CA implemented cannot be seen.	C
g)	Has the document of risks and opportunities been updated based on non-conformities found?		No, it has not been updated.	NC
10.3	**Continual Improvement**			
a)	Is there a procedure as a guideline for continuous improvemement of the QMS?	*1) Write doc # and its revision #. 2) Check what tool is used to identify potential nonconformities (PFMEA).*	Yes, there is a procedure (QP-022, Rev A/0) as s guideline to continuously improve the QMS.	C
b)	Dees the organization consider results of KPIs and evaluate them to determine necessity of improvement?		Yes, KPIs are analysed, but more specifically customer satisfaction. Cannot see further action to improve this satisfaction.	I

PROQC INTERNATIONAL	ISO 9001:2015 Quality System Audit	Rev.
	FACTORY PHOTOS	13

Supplier Name	Audit Date	Report No.
XXXXXXXXXXXXXXXXXXX	XXXXXXXXXXXX	XXXXXXXXXXX

Photos were removed due to confidentiality.		
Photo 1		Photo 2
Photo 3		Photo 4
Photo 5		Photo 6