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# Knowles Supplier Quality Manual

For distribution to all current and prospective Suppliers

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Cor	ntents Knowles Supplier Quality Manual	1
1.0	Purpose	4
2.0	Scope	4
	Knowles Quality Policy	4
	Environmental, Occupational Health and Safety Policy	4
3.0	Acronyms and Definitions	5
4.0	Supplier Interface and Communication	5
5.0	Supplier General Expectation and Requirements	6
	5.1 Supplier Code of Business Conduct	6
	5.2 Quality and Environmental Management System	7
	5.3 Hazardous Material and Substance Management	7
	5.4 Conflict Minerals Requirement	8
	5.5 Supply Chain Security	8
6.0	Supplier Approval and Classification	9
7.0	Material / Component Qualification	9
	7.1 New Part Quality planning and qualification	9
	7.2 Specification Review	10
	7.3 Reliability	10
	7.4 Failure Modes and Effects Analysis	10
	7.5 Control Plan	11
	7.6 Measurement System Analysis	11
	7.7 Statistical Process Control (SPC)	12
	7. 8 Supplier Readiness Reporting	13
8.0	Production Requirement	



	8.1 Document Control and Retention	14
	8.2 Change Control and Change Notice	15
	8.3 Sub-Supplier Management	16
	8.4 Traceability	16
	8.5 Package, Storage and Delivery	17
	8.6 Ship to Stock	17
9.0	Supplier Quality Performance and Improvement	18
	9.1 Acceptance Sampling Plan	18
	9.2 Control of Non-Conforming Product	18
	9.3 RMA management	18
	9.4 Supplier Corrective Action	19
	9.5 Quality Performance Indicators and Measurement	20
	9.6 Continual Improvement	20
	9.7 Supplier Audit	21
	9.8 Supplier Scorecard	21
10	Escalation Process	22
11	Business Continuity Plan	23
12	Customer Specific Requirements	23
13	Reference Documents	24
14	List of Part Quality Control Instructions	25
	pendix A: Expectation and Requirement to Knowles Corporation Customer Mandated Supplier and/or stomer as Supplier	r
	pendix B: Special Requirements to Knowles Corp Medical Business Supplier (Refer to Section 6. oplier Approval and Classification)	26
Sur	pplier Acknowledgement	33



#### 1.0 Purpose

The purpose of this manual is to communicate Knowles expectations and requirements to potential and existing Suppliers.

# 2.0 Scope

Knowles relies on Suppliers to provide superior quality to ensure Knowles achieves complete customer satisfaction and meets the goals stated in the Knowles Quality and Environmental Policies. This manual describes Supplier requirements, the processes used for Supplier approval, product qualification process, Supplier process control system, Supplier shipment acceptance requirements, in addition to ongoing Supplier performance evaluation.

# **Knowles Quality Policy**

Knowles ensures consistent delivery of our products and services based on our Quality Management System that achieves design integrity, efficient manufacturing and cost effective on-time delivery. We evaluate the effectiveness of the Quality Management System to enable compliance with all applicable requirements. We use continuous measurable improvement as a proactive means to achieve customer satisfaction.

# Environmental, Occupational Health and Safety Policy

Knowles is committed to protect the environment and provide safe and healthy working conditions in all aspects of our products, processes and related business practices. Our Environmental, Occupational Health and Safety Management Systems minimize pollution, work-related injuries and ill-health by eliminating hazards and reducing OH&S risks.

We will maintain our EHS Management Systems based on ISO 14001 and ISO 45001 standards and continually improve their effectiveness. We are committed to fulfill all EHS compliance obligations and other requirements wherever we operate. We will advocate for EHS awareness, participation and consultation among workers and other interested parties.



# 3.0 Acronyms and Definitions

ASL - Approved Supplier List
CM - Category Manager

CMRT - Conflict Minerals Reporting Template

COC - Certificate of Conformance
CSR - Corporate Social Responsibility

Cpk - Statistical Measurement of Process Capability

DPPM - Defective Parts per Million

DRC - Democratic Republic of the Congo

FAI - First Article Inspection

FMEA - Failure Mode Effect Analysis

GR&R - Gage Repeatability and Reproducibility
HSPM - Hazardous Substance Process Management

IQC - Incoming Quality Control
LAR - Lot Acceptance Rate

MSA - Measurement System AnalysisMSDS - Material Safety Data Sheet

NCMR - Non-Conforming Material Report
NPI - New Parts/Products Introduction

OTD - On Time Delivery

PPAP - Production Part Approval Process
RMA - Return Material Authorization
SCAR - Supplier Corrective Action Request

STS - Ship-To-Stock

SQE - Supplier Quality Engineer PCM - Process Control Monitor

# **4.0** Supplier Interface and Communication

- 4.1 Supplier Quality Engineer (SQE) is the Knowles quality contact person with Suppliers. SQE works with Suppliers on New Product/Process Introduction (NPI), communicating Knowles quality requirements, and driving quality improvement projects and performance with Supplier. In the event of Supplier quality issues, SQE will lead issue resolution.
- 4.2 Incoming Quality Control (IQC) performs incoming inspection to ensure only components meeting specifications are released for production. IQC will communicate with Supplier and



SQE on matters related to day-to-day work, including handling of non-conforming material disposition.

- 4.3 Category Manager is responsible for leading Supplier selection, Supplier development and maintaining the strategic and commercial relationship with Knowles Suppliers for all Knowles locations worldwide.
- 4.4 Engineering / R&D team is responsible for product design and technology roadmap requirement and communication in New Product / Process Introduction (NPI) stage.

# 5.0 Supplier General Expectation and Requirements

#### **5.1 Supplier Code of Business Conduct**

Knowles Corporation and its subsidiaries worldwide (collectively, "Knowles") understand that our success depends on our reputation for ethical business performance and performing our jobs honestly, diligently and with integrity, in compliance with all applicable laws and regulations. Consistent with our commitment to conduct business fairly and honestly, we seek out business partners who share in our culture, values and business practices.

Knowles' Social Responsibility requirements are aligned with International guidelines in the Responsible Business Alliance (RBA) Code of Conduct. Suppliers are required to have similar policies and practices in place which support a positive workplace environment.

Supplier Code of Conduct and RBA Code of Conduct –A standard for Supplier to perform their operation and conduct ethical business performance along the 5 pillars of:

- A. Labor
- B. Health and Safety
- C. Environment
- D. Ethics
- E. Management System

Knowles key Suppliers responsible for continuous CSR improvement based on Supplier Code of Conduct and RBA Code of Conduct and for communicating the contents of the Supplier Code to its officers, directors, employees, agents, subcontractors and sub-tier sources who are involved in the procurement and production process related to products and services provided to



Knowles. If a Supplier violates any of the requirements contained in this Supplier Code, Knowles may immediately terminate its supply relationship with that Supplier.

Knowles requires Suppliers to self-assess compliance to Knowles Supplier Code on a regular basis to ensure compliance (Form 06.09-10 and Form 22-01-01). Knowles will regular perform on-site audit as necessary.

# 5.2 Quality and Environmental Management System

A current and recognized quality system is essential to start doing business with Knowles. Supplier is required to maintain an effective Quality Management and Environmental Management System that conforms to the current ISO 9001 or equivalent standard at a minimum, satisfy the requirements of one or more of ISO 14001, ISO 45001, IATF 16949, TL 9000, IECQ QC 080000 or other internationally recognized Quality Management System. Supplier must furnish a copy of their Certificate, Quality Manual and supporting documents / procedures if requested.

# 5.3 Hazardous Material and Substance Management

Knowles requires Suppliers to comply with Knowles Supplier Hazardous Substance Free Handbook (HSF Handbook). When a new part/material is being considered, the Supplier will be asked for the material composition and part weight. This is accomplished by the Supplier completing a Material Composition Declaration (Form 00.07-01-6) along with providing substantiating evidence for the claims.

Substantiating evidence may be MSDS sheets, third party Laboratory test reports and engineering notes that help explain any calculations used in making the declaration for the homogenous materials used in making the part or packaging material.

If the Material Composition Declaration (Form 00.07-01-6) is not completed during the Request for Quote process, the form is sent to the Supplier for completion when the new part/material is ordered for the first time. Failure to complete Hazardous Material / Substance review process may prevent the Supplier from being approved.

Supplier shall report conformance to HSF Handbook by completing Certificate of Non-Use of Hazardous Substances (Form 00.07-01-8).



# **5.4 Conflict Minerals Requirement**

In the Democratic Republic of the Congo (DRC) or adjoining countries, the mining of minerals used to produce tantalum, tin, tungsten and gold (known as 3TG minerals) has been linked to funding armed groups engaged in violent conflict in the DRC region.

As part of Knowles's commitment to social responsibility and compliance with Rule 13p-1 under the Securities Exchange Act, it is our goal to only use 3TG minerals in our products that do not directly or indirectly finance or benefit armed groups in the DRC region.

In addition, Knowles has established responsible minerals sourcing practices for cobalt in response to reports of child labor and other social issues.

We are taking steps to ensure the use of conflict-free and ethically-sourced minerals in our supply chain by expecting our Suppliers to:

- Adopt a conflict minerals policy that is consistent with this Policy and require their direct and indirect Suppliers to do the same.
- Exercise due diligence with relevant Suppliers on the source and chain of custody of 3TG minerals consistent with the OECD Due Diligence Guidance for Responsible Supply Chains of Minerals from Conflict-Affected and High-Risk Areas.
- Identify smelters/refiners associated with the 3TG mineral supply chain for our products.
- Transition to certified conflict-free smelters / refiners.

Suppliers should survey their supply chain using the CMRT, assess smelter information for accuracy and completeness, and follow-up with their Suppliers as needed before furnishing the CMRT to Knowles.

#### **5.5** Supply Chain Security

All participating Suppliers must have security policies in place to ensure that they comply with the requirements for importing and exporting. Knowles has a partnership with US Customs-Trade Partnership Against Terrorism (C-TPAT). Suppliers exporting to US must fill out a Supplier Security Questionnaire Form (Form 06.11-07) provided by the Category Manager, annually. Supplier must also disclose if they participate in their local countries security program.



# 6.0 Supplier Approval and Classification

All Suppliers of production materials to Knowles must be qualified by the Supplier Approval Process. The approval process consists of three parts: Commercial assessments, Technology capability assessment and Quality System assessment. The Supplier will be listed on the Approved Supplier List based on a successful Supplier assessment result, shipped material / components passing specific qualifications as outlined by Knowles, and Supplier's compliance with 5.0, Supplier General Requirements.

Knowles classifies Suppliers as either Strategic Supplier, Preferred Supplier and Approved Supplier.

For all Medical Device Projects (Per Knowles Drawing) Medical Business Suppliers shall adhere to Appendix B: Special Requirements to Knowles Corp Medical Business Supplier, in addition to all contents of the Knowles Supplier Quality Manual.

## 7.0 Material / Component Qualification

Knowles maintains an Approved Supplier List (ASL) for each production product. The approved Supplier can ship material or components to Knowles for qualification. Knowles expects Suppliers to provide component qualification reports and supporting material in all affected phases that may be from but not limited to NPI phase, design change phase and Supplier change notification process.

ASL suppliers and customer assigned partners must pass Knowles qualification plan and evaluation requirements before production phase.

For certain critical material or components, the Knowles Engineering team, CM and SQE will work with Suppliers to complete each evaluation stage of New Product Introduction.

# 7.1 New Part Quality planning and qualification

Knowles encourages its Suppliers to adopt an Advanced Product Quality Planning process for New Product Development. Suppliers are expected to generate a formal process for project planning and new part introduction in accordance with AIAG APQP guidelines (or equivalent) for Knowles' product development programs. The purpose of APQP is to provide a clear and robust framework to ensure manufactured products will consistently meet Knowles and Knowles' customer's requirements. It is the responsibility of the Supplier to submit the required documentation to Knowles SQE to ensure that every supplied material and



component meets engineering and process control requirements prior to receiving shipment at Knowles. Knowles required documentation is defined in 7.8, Supplier Readiness Reporting.

## 7.2 Specification Review

Supplier shall review Knowles' prints and related specifications carefully. Supplier shall ensure understanding and meet all requirements before submitting quotation or producing samples. If any constraint or foreseeable quality risk is noted in the print and/or specification requirement, the Supplier shall contact Knowles Engineering and SQE or CM to communicate all issues and recommend improvement proposal (DFM or EQ) for Knowles by formal email.

## 7.3 Reliability

Knowles defines reliability test plans in the NPI phase. Reliability testing demonstrates that product design and manufacturing processes meet quality compliance and do not contain flaws that would lead to early failure in the field. Knowles SQE will work with suppliers to identify reliability tests plans; and for certain critical components and materials, Ongoing Reliability Testing (ORT) plans (as defined in Knowles Parts Quality Control Instruction document). All test reports need to be kept as a Quality record.

If any ORT failures occur, the Supplier must immediately inform Knowles SQE (no later than 24 hours) via email and phone call. All affected lots must be quarantined (including any prior shipments), and Supplier must communicate the disposition and get Knowles approval for affected lot(s) and inventory.

## 7.4 Failure Modes and Effects Analysis

Supplier shall conduct a systematic and comprehensive FMEA to identify and address all potential issues in the product development phase (DFMEA) and each manufacturing process step (PFMEA). The FMEA process includes system analysis, failure analysis, risk mitigation, and considers all reasonably foreseeable potential failure modes in the Design and Manufacturing Process. Suppliers must implement proactive corrective actions to eliminate potential identified failures. Suppliers shall have regular FMEA document reviews and update regularly, especially in the event of Design or Process change.



#### 7.5 Control Plan

The process Control Plan must include all manufacturing processes including: in-house process, external process, inspection, packaging and shipping. The objective of the process control plan is to ensure measures are implemented to strive for zero defect manufacturing through PFMEA execution. The Control Plan must cover, but is not limited to the area listed below.

- Process parameters and quality monitoring: CTQ, FAI and SPC parameters. Inspection methods, sampling frequency and sizes. Control Plan parameters should be based on process capability, likelihood of non-conformance, risk severity, failure occurrence, failure detection and process stability.
- Data collection and Analysis: Knowles encourages Suppliers to have automated data collection for in-process parameters and quality data. The data should be maintained and analyzed by Supplier, and may be requested by Knowles SQE.
- Tool/Fixture/equipment maintenance: The process Control Plan should define maintenance schedules and collection of performance data for tools, tooling, fixtures, jigs, and equipment.
- Measurement System Analysis: Supplier shall maintain effective measurement systems for inspection tools, gauges, testing devices and measuring instruments. (See 7.6)

#### 7.6 Measurement System Analysis

Suppliers have the responsibility to verify effective measurement systems and ensure produced material or components meet specifications. Suppliers must have the capability to monitor and measure all characteristics of the material/component print(s) and related specifications. All measurement devices shall be identified and tracked to reflect the latest calibration status. The calibration shall be traceable to national/international calibration standards.

Suppliers must establish measurement systems and perform analysis to ensure measurement variation is acceptable for product and process characteristics. For variable gages, the quantification of measurement system analysis includes, but may not be limited to, accuracy/bias, Gage Repeatability & Reproducibility (Gage R&R) and stability / linearity. For attribute gages, the Attribute Gage Study is required.



Suppliers are required to perform Gage R&R studies for each type of gage on critical specifications prior to submitting First Article Samples to Knowles. The guidelines for acceptance of % gage R&R are:

% Gage R&R Value	Variable Gage	
≤10%	Acceptable.	
>10% ≤ 30%	Marginal – The measurement system may be acceptable based upon importance of engineering / manufacturing application, cost of gage, cost of repairs.	
	Supplier should have continuous improvement plan.	
>30%	Not acceptable – Supplier <u>must</u> correct it.	

Suppliers must work with Knowles to complete gage correlation studies as required. SQEs will provide the correlation study plan for Knowles to correlate its measurement with Supplier's measurements.

Suppliers shall ensure measurements, methods, and test parameters are well understood and correlated with Knowles expectations.

#### 7.7 Statistical Process Control (SPC)

Suppliers are required to apply effective statistical methods to monitor and improve processes. Statistical Process Control (SPC) is a methodology for charting the process and quickly determining when a process is out of control. Suppliers shall monitor the process performance against a calculated set of control limits and assess actions to control. For each out of control condition, Supplier shall have a documented process in place to identify the cause and action response, material review process and disposition method. Records should be made available to show evidence of in-process control, action response to out of control conditions, and any action taken.

#### 7.7.1 Process Capability

Capability Studies and Statistical Process Control shall be performed in accordance with the rules defined in the latest edition of the AIAG PPAP and SPC manuals.

#### **Initial Capability:**



Products are taken from pre-production at the manufacturing location(s) and analysed statistically. Parts from each unique production process e.g. duplicate assembly line and/or work stations, each position of a multiple cavity die, mould or pattern, shall be measured and representative parts tested. Knowles requirements on initial capability studies are Min 1,67 Ppk, a Pp of minimum 2,0 can also be required or mutually agreed Pp and Ppk with Knowles SQE.

For non-critical dimensions a minimum Ppk of 1,33 may be required or mutually agreed Pp and Ppk with Knowles SQE.

#### On-going Control:

For critical or agreed characteristics where the process can be adjusted during the production run, SPC will be used to control the process output. If nothing else is agreed, the Knowles requirement on serial production capability is minimum 1.33 Cpk or mutually agreed Cp and Cpk with Knowles SQE.

In the event of a noncompliance with the capability requirements, the Supplier is required to provide an agreed action plan and the capability results shall fully comply with the requirements. These actions must be fully documented in the Control Plan and the process FMEA.

# 7. 8 Supplier Readiness Reporting

A First Article and / or Production Part Approval report is required prior to the first shipment of production material to Knowles, or when a product undergoes a change. The Supplier must perform its internal Production Part Approval Process (PPAP) or Knowles Supplier Ready2X process via Ready2X Report (Knowles document number : Form 06.26-01) for every New Product Introduction phase.

Knowles Supplier Part Readiness requirements may vary with the submission phase of the NPI process. Suppliers are required to provide an updated PPAP document or Ready2X Report based on current development phase or revision change. Knowles SQE will notify Supplier when a part is qualified and approved. Only products that are approved by Knowles may be shipped. In the event that a submission cannot be approved, the Supplier will be informed of the discrepancies and are required to submit a corrective action. Once corrective action(s) is complete, and the discrepancies has been corrected, the Supplier must contact the Knowles Requestor to schedule a date for re-submission. Questions regarding First article report or Ready2X submission requirements or submission status should be directed to the Knowles contact requesting submission.

Copies of all requested First Article or Ready2X (or PPAP) submissions must be maintained by the Supplier and be readily available for review upon request.



# **8.0** Production Requirement

#### 8.1 Document Control and Retention

Supplier must establish, maintain and document procedures to control all Quality Management System documentation and data within the quality management system. Unless otherwise specified by Knowles, the Supplier is responsible for maintaining documents and records in accordance with the below requirements.

- Supplier shall have the latest revision of documents available at all appropriate locations.
- Records shall be kept in paper or electronic file and properly labeled to identify the type
  of record.
- If Quality and Environmental records are stored in electronic format, the system shall be securely stored to prevent any unauthorized access, alteration or deletion. Systems shall also be properly protected and backed up regularly.
- Knowles technology documents, drawings and specifications (prints) must be governed by NDA between Knowles and the Supplier.

#### Record and Sample retention periods:

- Product qualification reports and ongoing reliability test reports should be kept for a minimum of 15 years.
- Supplier Change Notifications Document should be kept for a minimum of 10 years.
- Incoming, in-process test data, final inspection reports, Certificate of Conformance reports (CoC), hazardous substance test reports, yield and scraps report should be kept for a minimum of 7 years.
- Other quality and environmental records should be kept for a minimum of 5 years.
- Reliability Test samples, IQC samples, OQC samples should be kept for a minimum of 2 years.

The above time periods are to be considered as minimum. Record retention management systems should be in place and ensure records are maintained by applicable law, regulations, standards and agreements.



# 8.2 Change Control and Change Notice

Product Change Notices are the mechanism that Suppliers must use to inform Knowles of a proposed product changes, product discontinuation, end of life, etc. The information received in the notice is reviewed to assess impact. Suppliers are required to submit a Product Change Notice for ANY proposed change including, but not limited to, the following:

- a. Change in manufacturing process
- b. Change in material or change in material source
- c. Change in manufacturing location
- d. Change in part construction / design (i.e. Die Shrink)
- e. New or modified tooling
- f. End of Life

Submission of a Product Change Notice to Knowles does not indicate approval of a proposed product change. Knowles reserves the right to reject any proposed change, and/or require additional information / data be supplied, or seek customer(s) concurrence prior to granting approval. The Supplier will be notified if any of these conditions applies to a proposed product change, and the requirements for obtaining approval. Suppliers must maintain records of the date of implementation in production of each change.

In the event a Supplier has a product change request, the Supplier must submit a completed Supplier PCN Management Form (Form 06.25-01) to Knowles Buyer, SQE and CM by email as soon as the project is known. For a normal PCN, Suppliers are required to initiate the PCN at least 3 months prior to the change implementation. For EOL or high risk PCN changes, Suppliers are required to initiate the PCN at least 6 months prior to the change implementation. Some components or commodities may require a longer time to achieve full approval of changes. As a general rule, Suppliers should notify Knowles of required changes as early as possible and obtain agreement on the implementation timing. Supplier will then work with Knowles SQE to complete the change evaluation, qualification and implementation date.

Note: will attached Form 06.25-01 in appendix



#### 8.3 Sub-Supplier Management

Suppliers are responsible to develop and strictly maintain a robust sub-Suppliers quality management system to assure the quality of purchased materials. Suppliers shall ensure their sub-Suppliers comply to all the clauses in 5.0 of this manual, and Knowles also expects Suppliers' sub-Supplier management controls to include, but not be limited to, the listed below.

- Supplier planning, classification and selection
- Conducting on-site process audits at sub-Suppliers
- Drawing, Revision and Configuration control
- Material and Component Qualification
- Control of sub-Suppliers' processes and capabilities
- Performance monitoring
- Change control and notification
- Control of Non-conforming material, corrective and preventive action
- Lot control and traceability systems
- Education programs to communicate to sub-Suppliers about Knowles expectations and requirements

In the event of a significant quality incident, Knowles reserves the right to audit the quality management system of sub-Suppliers.

# 8.4 Traceability

Suppliers are required to establish and maintain documented traceability procedures for identifying materials from receipt, through all stages of production and delivery. Suppliers shall execute a traceability system that takes into account reasonable production lot size and anti-mixing mechanisms. Traceability records must be maintained and readily available for every production lot. Supplier material traceability definition shall be agreed upon with Knowles SQE and identifiable information may include, but is not limited to, the following:

- Material Supplier name
- Material Part Number



- Material Revision
- Production lot code, batch code, serial number
- Production date, production time
- Machine, Tooling, Cavity Number, Fixture information
- Process parameters
- Production shift information
- Quality information

In the event of a significant quality incident, Suppliers must share traceability records and conduct commonality analysis within 24 hours.

## 8.5 Package, Storage and Delivery

Suppliers shall have package, storage and delivery procedures in place. Suppliers shall package all products in accordance with the specifications, Knowles instructions and applicable regulatory requirements. The packaging must comply with import / export customs regulations, industry specifications, international standards and all applicable governmental, environmental and regulatory regulations.

The Supplier shall implement a First In First Out (FIFO) system for disbursement of product from storage. All products shall be packaged to prevent damage and deterioration from shipping to storage. Knowles holds the Supplier responsible for product delivery quality.

Knowles may require Suppliers provide packaging instructions and methods, product shelf life and storage requirement information in the product qualification stage.

# 8.6 Ship to Stock

The ship to stock program exempts Supplier's products from the Knowles IQC sample inspection process based on following criteria.

- Supplier's scorecard
- Supplier audit result
- Knowles IQC Lot Acceptance Rate



Once a quality issue is encountered (e.g. incoming inspection rejection, customer complaint, process abnormality which is proven a Supplier material issue or specification changed without Knowles approval), Knowles will revoke the Ship to Stock program for the product.

# 9.0 Supplier Quality Performance and Improvement

# 9.1 Acceptance Sampling Plan

Supplier shall inspect and test products prior to the shipment to Knowles. The typical acceptance level for all sampling plans is (C=0), please refer to **Knowles Part Quality Control Instructions** for specific requirements.

# 9.2 Control of Non-Conforming Product

Suppliers shall establish an effective system for non-conforming material or product control. The system shall include identification, quarantine, final disposition and prevention from unintended use or delivery. The non-conforming product control shall include control for material/product returned from Knowles. Supplier must have a record and document for the evaluation and disposition of non-conforming products.

In the event non-conforming material or product is identified at Knowles, it will be rejected and Knowles will quarantine per the Material Review Board process. Knowles SQE will notify the Supplier of such occurrence, and the Supplier is required to immediately provide quality data of affected lot(s) to ensure no additional suspected shipments to Knowles.

Any material/product rejected due to the fault of the Supplier will be dispositioned per the following:

- Supplier arranges sorting at Knowles facility
- Knowles returns the entire lot of non-conforming product to Supplier
- Knowles performs sorting and reserves the right to charge the sorting cost or rework cost to Supplier

#### 9.3 RMA management

Suppliers shall have an established Returned Material Authorization (RMA) system. Once a disposition has been made by either Knowles or Supplier to return product, Supplier shall



collaborate with Knowles to execute the material / product return and related financial credit or replacement process. Suppliers are required to provide an RMA number to Knowles within 24 hours upon a Knowles request to return the materials to Supplier.

#### 9.4 Supplier Corrective Action

Suppliers shall establish and maintain corrective and preventative action systems in compliance with quality management system requirements. Suppliers must to be able to support Knowles with failure analysis and apply problem solving methods that may include, but are not limited to: process mapping, commonality analysis, 3 Legged-5 Whys analysis, Pareto Charts, Cause and Effect Diagrams, Hypothesis Testing.

Once Knowles detects a nonconforming material event, Knowles SQE will provide the Raw Material Nonconformance Feedback Form (Form 1409-04) with nonconformance information to the supplier. The supplier is required to collaborate with Knowles SQE to document the improvement action(s) with 8D methodology via Knowles SCAR format.

Knowles SQE may release SCARs to Suppliers for quality issues that may include:

- Supplier material issues causing a Knowles Customer Complaint or Reliability issue
- Chronic issues including: Repeat functional, dimensional or CTQ issues
- Any violation to legal requirements which (or potentially) causes line down or impact Knowles shipments, or non-conformance to Knowles customer requirements
- Non-conformance to Knowles Hazardous Substance Free (HSF) Requirement per Knowles HSF handbook
- Non-conformance to Knowles and customer's specification requirement
- Supplier violates 8.2 Change Control and Change Notice Requirements
- Monthly IQC/LAR result does not meet target
- Knowles has Major finding during on-site Supplier audit
- Supplier missed-shipment and the issue caused Knowles line-down or impacted Knowles on-time delivery to customer
- Counterfeit issue



Knowles may also utilize the 8D methodology (SCAR) to document continuous improvement actions for below scenarios:

- If the material poses a potential risk to product failure, customer complaint or a systemic defect
- If Knowles encounters a process issue, but Supplier's material meets Knowles specification, Knowles SQE will collaborate with Supplier for continuous improvement in a mutually agreed timeline. Knowles will use the <a href="SCAR-Improvement">SCAR-Improvement</a> report as record.
- SCAR-Improvement will not be rated in Supplier scorecard review.

# 9.5 Quality Performance Indicators and Measurement

Knowles has developed Supplier Key Performance Indicators (KPI) which are used for quality performance monitoring. Knowles monitors material / component quality to ensure material / component quality meet Knowles requirements. Knowles SQE will continually assess and work closely with Suppliers to ensure quality requirements are met. Knowles evaluates Supplier quality performance using following indicators:

- Knowles IQC: LAR (Lot Acceptance Rate)
- Supplier material DPPM
- SCAR and repeat case quantity
- SCAR turnaround time
- Customer complaints
- Supplier audit results
- Supplier Scorecard

#### **9.6 Continual Improvement**

Knowles expects all Suppliers to have an established continuous improvement program that benefits customers with regards to quality, delivery, cost and services. The objectives and targets should be established based on business plans, management systems, process capability, product quality and customer satisfaction.



Knowles may perform on-site verification of improvement actions and may provide subsequent recommendations for continuous improvement. The Supplier is expected to use statistical tools and techniques to analyze process capability, process parameters, non-conformance data, scrap and downtime. The quality improvement goal is to reduce process variation, product quality variations and achieve Knowles's quality improvement expectations.

Suppliers should be able to demonstrate a positive trend in reducing incidents and repeat occurrences. Knowles will set improvement objectives and work with selected key Suppliers to monitor objectives for improvement in a mutually agreed timeframe.

#### 9.7 Supplier Audit

Knowles SQEs routinely conduct on-site audits to ensure the effectiveness of the Supplier's quality management system and process capability. The Supplier shall make its facility readily available for on-site audits upon notification from Knowles. It is the Supplier's responsibility to be well prepared for the audit, including submission of self-assessment survey checklist in advance.

The type of audit will depend on the intended purpose and scope, which may fall under the following categories:

- New Supplier and Periodic Assessment: The audit scope includes Quality management systems, Hazardous Substance Process Management and Corporate Social Responsibility
- Process Audit: The audit scope includes NPI process, new process and the critical process that may impact quality or reliability
- Supplier Change Notification pre-implementation verification audit
- Ad hoc Auditing: Supplier poor performance, customer requirement, or other reason

In addition to the listed scopes, Suppliers are expected to routinely conduct internal audits for their NPI and production process.

# 9.8 Supplier Scorecard

Supplier performance is measured based on several elements, with each element weighted to performance metrics. The Supplier rating is based on a weighted result of all element combinations, and these elements include Quality, Technology, Cost and Delivery. Knowles SQE reviews Supplier scorecards on a quarterly basis for Quality, Cost and Delivery follow by



leading a quarterly scorecard review meeting. The overall score determines category based on the table below:

Supplier Scorecard Performance	Overall Score
Excellence	≥ 85%
Good	≥ 70% - < 85%
Improvement Needed	≥ 60% - <70%
Unacceptable	< 60%

- If a Supplier scorecard rating is in the "Improvement Needed" status, Knowles will communicate the improvement areas, and the Supplier is required to provide improvement plan(s) to Knowles and implement per agreed timelines.
- When the Supplier scorecard rating is "Unacceptable", the Supplier shall provide an improvement plan within an agreed upon timeframe. Suppliers are required to tighten in-process and/or outgoing detection controls until significant improvement is achieved. In the event a Supplier falls into "Unacceptable" rating for two consecutive quarters, Knowles may initiate an on-site audit, followed by necessary actions which may include stop shipment or disqualification from Knowles Approved Vendor List.

#### 10 Escalation Process

Suppliers shall establish escalation plans to alert Knowles of any process, delivery, or quality issue that may impact Knowles. The plan shall include a plan of action, communication plan, escalation procedure and roles and responsibilities. The purpose of the escalation process is to ensure all stakeholders are informed of the issue and in agreement with the resolution.

Suppliers are required to share their escalation plan and inform Knowles if there are any changes. If any changes are required, senior management responsible for product quality, or company ownership, shall notify Knowles via email within 14 working days.

If the Supplier identifies a delivery issue, the Supplier must trigger the escalation process and notify Knowles Buyer and/or CM via phone call and email within 24 hours. If Supplier identifies process variation that impacts product quality or reliability, the Supplier must trigger the escalation process and notify Knowles SQE via phone call and email within 24 hours.



**Level 1 review**: Supplier representative and Knowles buyer / SQE representative.

**Level 2 review**: Supplier Management and Knowles CM / SQE Management level.

For each level, the Supplier is required to provide performance deviation information and submit appropriate action plans to Knowles for agreement.

# 11 Business Continuity Plan

Supplier shall prepare a business continuity and disaster recovery plan to ensure continued supply of products to Knowles, with no interruptions to supply / delivery. The plan shall be reviewed on an annual basis to ensure valid contingencies are in place. Knowles expects Suppliers to have a comprehensive crisis management plan to deal with all potential scenarios (e.g. fire, flood, storm damage, chemical spill, earthquakes, material shortage, capacity constraint, etc). If Supplier identifies a contingency or business interruption issue that will impact Knowles, the Supplier shall apply an escalation management plan and notify Knowles CM within 24 hours (with a risk mitigation plan).

## 12 Customer Specific Requirements

In the mass production phase, Knowles may receive additional customer specific requirements from its customer. Suppliers are to ONLY receive such specific requirement from Knowles, and are expected to provide capability evaluation and technical suggestions for Knowles upon receiving the requirement. In the event of a concern to comply, it is the Supplier's responsibility to inform Knowles of the challenges to comply, with a proposed solution.



# 13 Reference Documents

00.07-01	Supplier Hazardous Substance Free Handbook
00.07-01-3	Supplier Declaration of Compliance for REACH Regulation
00.07-01-6	Material Composition Declaration
06.09-01	Knowles Supplier QMS Audit Report and Checklist
06.09-02	Knowles Supplier HSPM Audit Report and Checklist
06.09-10	Knowles Supplier Social Responsibility Self-Audit Checklist
06.11-07	Supplier Security Questionnaire
06.11-08	SiSonic Supplier Change Request Workbook
06.24-01	Supplier Scorecard - Quality
06.25-01	Supplier PCN Management Form
06.26-01	Knowles Supplier Ready2X Report
1409-01	Knowles Supplier 8D Report
1409-04	Raw Material Nonconformance Feedback Form
22.01-01	Suppliers Declaration on Knowles Supplier Code of Conduct



# 14 List of Part Quality Control Instructions

06.11-03-04	IC & OSAT
06.11-03-05	MEMS
06.11-03-06	PCB
06.11-03-07	Carrier Tape & Reel
06.11-03-08	Ероху
06.11-03-09	Solder Paste
06.11-03-10	Plating
06.11-03-11	HHT DPC Substrate
06.11-03-12	HHT FPC
06.11-03-13	HHT Litz Wire & Cable
06.11-03-14	HHT Coil
06.11-03-15	HHT Plastic Rod & Shim
06.11-03-16	HHT Metal Stamping
06.11-03-17	HHT Terminal Tab
06.11-03-18	HHT Magnet
06.11-03-19	HHT Circuit



# <u>Appendix A: Expectation and Requirement to Knowles Corporation Customer Mandated Supplier</u> and/or Customer as Supplier

# **Quality Responsibility**

The customer holds the responsibility for:

- The type of raw materials
- Material grade
- Appearance acceptance criteria (color, surface roughness, texture...etc)
- Material compliance
- Bio-compliance and FDA requirements

The customer is also accountable for supplier qualification and material qualification for non-turnkey projects. Knowles is responsible for dimensional measurement and material cosmetic inspection. In the event of non-conformance, Knowles SQE works with the supplier and customer to improve the product quality. If necessary, escalate to Corporate QA and/or Category Manager for further assistance.

# **Quality Criteria**

During the NPI stage (before Product Verification Test stage), the customer is responsible to:

- Provide Knowles with the latest quality criteria and Piece Part's specification for Knowles and the supplier to comply to. In an event the customer's criteria/specification(s) is absent, Knowles' general quality criteria should be adhered to for material inspection, measurement, and testing.
- Align acceptance criteria/specifications and resolve open issues with their consigned supplier.

## **Quality Agreement**

Knowles Supplier Quality Manual document (06.11-03) is distributed to all Knowles suppliers for compliance. The supplier is expected to sign off on the acknowledgment receipt on page 26. When applicable, both parties (Knowles and its suppliers) will follow the quality agreement with Knowles customer.

## **Supplier Audit**

Supplier audit is required to ensure that new suppliers can meet Knowles' and its customers' requirements, including quality standards, financial viability, and ownership structure.

Knowles will arrange an on-site audit or assessment for new suppliers appointed by customers for full turnkey projects. Customers are encouraged to share their supplier audit reports with Knowles to manage suppliers effectively.



# **Material / Component Qualification**

Material and component qualification is critical, and suppliers are expected to provide comprehensive reports and supporting documentation during all affected phases, including the NPI phase, design change phase, and supplier change notification process. For more information, please refer to section 7.0 of QPD 06.11-03, Knowles Supplier Quality Manual.

Knowles will carry out a standard material / component qualification process which sample submission from supplier, qualification build in Knowles and reliability is mandatory in Knowles.

# Reliability, Customer specification, Green compliance and Biocompatibility Requirement

Materials/components print/drawing meets the following requirements:

- ✓ Reliability
- ✓ Functional and application requirement per customer specification
- ✓ Green Compliance (where applicable)
- ✓ Biocompatibility (where applicable)

The supplier is responsible to provide all relevant information to support the qualification of materials/components.

# **Change management**

The supplier must submit a Product Change Notice for any proposed changes, including but not limited to:

- a) Changes in manufacturing processes
- b) Changes in materials or material sources
- c) Changes in manufacturing location
- d) Changes in part construction/design (i.e., Die Shrink)
- e) New or modified tooling
- f) End of Life

Note: Refer to QPD 06.25 appendix 8.2 for the change notification period.

On customer owned design VAM (value added assemblies) assemblies and components, (excluding Knowles Microphone and receiver), pre-approval is required from the customer for any change in VAM component/material initiated by the supplier. Knowles should also be notified on change per Knowles SPCN (Supplier Process Change Notification) notification process requirement.



# Knowles' incoming inspection and supplier CoC/OQA

Knowles IQC adheres to acceptance criteria aligned among customer, supplier, and Knowles for material incoming inspection. Below are guidelines of different sampling plan for different product life cycle:

- During NPI, sampling check AQL=0.4, C=0 is practiced
- Approved for Mass Production parts, AQL=0.65, C=0 is practiced

The supplier shall tighten the inspection sampling plan during the development stage and the supplier inspection sampling plan shall not be less stringent than Knowles IQC sampling plan for approved mass production parts. Lastly, suppliers must submit their CoC/OQA report with each part's shipment.

# Material quality issue and SCAR (Supplier 8D)

In the event of a material quality issue, the subsequent improvement actions must be documented in an 8D format and submitted to Knowles or the customer within an agreed-upon timeline. Disposal of non-conforming parts follows the regulations below:

- Production use of parts will require the acquisition of a waiver or deviation from the customer.
- Rework or sorting costs for non-conforming material will be charged back to the supplier or customer following a final agreement between Knowles, supplier, and customer.
- Non-reworkable defective parts are to be returned to the supplier/customer or scrapped at Knowles. The supplier must provide a credit note based on the final agreement between Knowles, supplier, and customer.

The standard SCAR expected response time is as follows:

- ✓ Containment action (D3) within 48 hours of complaint or sample(s) receipt
- ✓ Identified root cause of event and escapee by 4<sup>th</sup> working days from complaint date
- ✓ Final SCAR report (D7) within ten working days of sample(s) or formal complaint from Knowles / Knowles Customer

Depending on the urgency and situation of the issue, Knowles SQE and supplier may determine an agreed timeline for SCAR submission, review, and closure.



Appendix B: Special Requirements to Knowles Corp Medical Business Supplier (Refer to Section 6. Supplier Approval and Classification)

#### **Quality System**

Supplier is required to maintain an effective Quality Management System that conforms to the current ISO 9001 or equivalent standard at a minimum, satisfy the requirements of ISO 13485.

# **Supplier Approval**

Finish good shall be classified as a class 1, 2, or 3 medical device as per applicable regulatory requirements by Knowles customer.

Knowles establishes supplier evaluation and selection criteria which is 1) based on the effect of the purchased product on the quality of the medical device; 2) proportionate to the risk associated with the medical device.

# Supplier audit

Knowles may conduct unannounced audit.

Knowles to implement on-site audit when necessary or as per applicable regulatory requirements.

#### Medical device file

When required, for each medical device type or medical device family, supplier shall establish and maintain one or more files either containing or referencing documents generated to demonstrate compliance with applicable regulatory requirements.

#### **Control of documents**

Obsoleted documents shall be retained for a period which 1) ensure that documents to which medical devices haven been manufactured and tested are available for at least the lifetime of the medical device as defined by Knowles customer but 2) not less than the retention period of any resulting record (see below Control of records), or 3) as specified by applicable regulatory requirements.

Documents include but not limited to:

- Material drawing
- Inspection and quality acceptance criteria

#### **Control of records**

The supplier shall retain the records for 1) at least the lifetime of the medical device as defined by Knowles customer, or 2) specified by applicable regulatory requirements, but 3) not less than two years from the medical device released by customer.



Records include but not limited to

- Material certifications
- Supplier Process Change Notification
- Outgoing inspection records
- Reliability test report and samples

#### Work environment and contamination control

The supplier shall document the requirements for the work environment needed to achieve conformity to product requirements or as required by Knowles.

The supplier shall document requirements for health, cleanliness and clothing of personnel if contact between such personnel and the product or work environment could affect medical device safety or performance.

For sterile medical devices, the supplier shall document requirements for the control of contamination with microorganisms or particulate matter and maintain the required cleanliness.

The Supplier shall identify the contamination risk and take actions to avoid contamination during the process of product realization.

# **Purchasing Information**

Knowles sends Knowles Supplier Quality Manual (SQM) to the supplier during new supplier development stage, supplier shall sign back the acknowledgement.

Knowles sends Knowles Supplier Change Notification letters to the supplier during new supplier development stage, supplier shall sign back the acknowledgement. The supplier shall notify Knowles of changes in the purchased product prior to implementation of any changes that affect the ability of the purchased product to meet specified purchase requirements

#### Identification

The supplier shall identify product by suitable means throughout product realization.

The supplier shall identify product status with respect to monitoring and measurement requirements throughout product realization.

If required by applicable regulatory requirements, the supplier shall assign Unique Device Identification (UDI) to the medical device.

The supplier shall document procedures to ensure that medical devices returned to the supplier are identified and distinguished from conforming product.

## **Traceability**



The supplier shall document procedures for traceability. These procedures shall define the extent of traceability in accordance with applicable regulatory requirements and the records to be maintained.

The records required for traceability include,

- Materials lot information
- Production information (equipment, operator, tool/fixture...)
- Process control and quality inspection result

# Particular traceability requirements for implantable medical devices

- Components
- Materials
- Conditions for the work environment used
- The name and address of the shipping package consignee.

#### **Knowles property**

The supplier shall identify, verify, protect and safeguard Knowles property.

Knowles property include but not limited to Material, Drawing, Equipment, fixture, Information.

# **Preservation of product**

Preservation shall apply to the constituent parts of medical device.

The supplier shall protect product from alteration, contamination or damage when exposed to expected conditions and hazards during processing, storage, handling, and distribution.

# Monitoring and measurement of product

The supplier shall monitor and measure the characteristics of the product to verify that product requirements have been met, and submit to Knowles when requested,

- Material compliance report
- Medical certification document
- Certificate of Compliance report (CoC)

Following shall be recorded and maintained as the evidence of conformity to the acceptance criteria

- The identity of the person authorizing release of product
- The test equipment used to perform measurement activates

For implantable medical devices, the supplier shall record the identity of personnel performing any inspection or testing.



# **Control of nonconforming product**

When nonconforming product is detected before delivery, the supplier shall ensure that nonconforming product is accepted by concession only if 1), the justification is provided, 2), internal and customer approval is obtained and 3), applicable regulatory requirements are met.

When nonconforming product is detected after delivery or use has started, the supplier shall notify Knowles as soon as nonconforming product is detected.

#### **Software and Process Validation**

Upon Knowles request:

- 1) Measuring and monitoring equipment software must be validated.
- 2) Non-verifiable process must be validated.



# **Supplier Acknowledgement**

knowles	Supplier Acknowledgen	nent			
Acknowledgement					
We acknowledge receipt and understand the requirements stated in Knowles Supplier Quality					
Manual. If there are any further concerns or queries regarding this document, we will contact you					
within 5 business days.					
Company Name					
Company Presentative					
Tile					
Date of Receipt					
Date of Acknowledgement		Company Stamp and/or Signatory			