Supplier Requirements Handbook

Handbook Application

This handbook applies to all suppliers that may or currently do provide materials, components, parts, and sub-assemblies that are incorporated into final products. Also included are suppliers of associated services that may affect product quality, such as design, delivery and calibration of measuring equipment, etc.

Exclusion: The procurement of office supplies, stationery, sundries and janitorial services/supplies are excluded from this requirement, as are repair/replacement parts, etc.

Supplier Requirements

1.0 QUALIFICATIONS

1.1 Quality Management System

All suppliers must have a documented quality management (QM) system to ensure their products conform to specified requirements or have a development plan for establishing an ISO 13485 or 9001 compliant system. The supplier is required to establish and maintain a quality system certified to the most current ISO 13485 standard or ISO 9001 standard and compliant with Good Manufacturing Practices. An onsite assessment of supplier may be conducted per the discretion of Quality and/or Sourcing based on qualification or performance metrics.

1.2 Qualifications

Committed and significant relationships with Stanley Healthcare's chosen suppliers are critical to our success. It is important, therefore, for Stanley Healthcare to be able to rely upon its suppliers to provide the materials and services needed to meet its customers' expectations.

Stanley Healthcare thoroughly evaluates each of its suppliers to determine the level of qualification in our supplier network. All suppliers will be issued a Supplier Handbook and are required to fill out and return Section 3 of the handbook.

2.0 Safety and Environmental Requirements

2.1 Government, Safety and Environmental Regulations

All products purchased must satisfy current Federal/State/Local governmental and safety constraints on restricted, toxic and hazardous materials; as well as environmental, electrical and electromagnetic considerations applicable to the country of manufacture and sale.

2.2 Environmental Communication

Stanley Healthcare requires its suppliers to communicate all environmental requests, concerns or any other environmentally related information to its Stanley Healthcare contact. The supplier shall submit a Material Safety Data Sheet (MSDS) with per purchase order.

2.2.1 Green Strategy

Stanley Healthcare requires its suppliers to review the products and services supplied to Stanley Healthcare to identify opportunities for improvement and minimization of potential environmental impacts, and to satisfy statutory, and regulatory requirements. This may include, but not limited to, the identification of less hazardous products, products that produce less waste, or products that are more amenable to recycling.

Stanley Healthcare encourages the purchase of recycled and environmentally preferred products in order to minimize environmental impacts in our work place whenever they perform satisfactorily and are available at a reasonable price.

2.2.2 RoHS Compliance, REACH. WEEE, Conflict Mineral

Where applicable the supplier shall state RoHS, REACH, WEEE, and/or Conflict Mineral compliance on the Declaration of Compliance with each purchase order.

Restricted substances for all suppliers must be declared per ES100118 Engineering Specification & Form for Restricted Substance Declaration. Suppliers must submit their Online Restricted Substance Declaration via the following:

- Go to restricted substance declaration system website (http://gsp.sbdinc.com)
- Create a login account.
- Complete online declaration form.
- Submit the declaration per instructions provided.

Additional restricted substances listed in Appendix A are additional materials that are not allowed in Stanley Healthcare medical products or components. Appendix A must be reviewed and confirmed by the supplier.

2.3 Continuous Improvement Process

Suppliers need to establish, maintain, and document a continuous improvement process with the focus on quality, delivery, cost, service, and technology. Stanley Healthcare requires that this activity be supported throughout the supply chain. Continuous improvement activities shall meet the intent of ISO 13485 or ISO 9001.

2.4 Corrective Action Request Requirements

Should deficiencies in quality be determined, the Supplier will receive notification in writing either through a Supplier Corrective Action Notice (SCAN) or Supplier Corrective Action Request (SCAR). SCAN's are simply a notification of an incidental error that does not directly affect the product form, fit, function and does not require the supplier to respond. An example would be where a SCAN would be issued is if the packing slip or certificate of compliance were not included in the shipment causing a delay in receipt. On the first occurrence a SCAN will be issued as a courtesy, recurrence will initiate a SCAR.

A Supplier Corrective Action Request (SCAR) will be issued when a product nonconformity is identified that directly affects the form, fit, or function of the product or if any of the requirements listed in this manual are not met by the supplier. In the event of a Supplier Corrective Action Request, the following measures are to be taken by the supplier without delay:

- An Immediate response, within 24 hours, acknowledging SCAR receipt and the product containment plan.
- Formation of an improvement team.
- Prompt initiation of an investigation.
- Determination of the cause of the deficiency, i.e. Root Cause analysis.
- Implementation of permanent corrective actions.
- Evaluation of the effectiveness of the corrective actions.
- An update of relative quality documents.

Reporting of root cause, corrective action plan and preventive action plan within 14 calendar days.

This process conforms to the 8-D or 5-phase process of corrective actions. The supplier will be notified of all costs resulting from deficiencies in its performance and will be fully liable for them.

2.5 Conditions of Acceptance

The parts supplied will be accepted only if they fulfil the parameters specified in the valid drawings and/or specifications. Damaged or contaminated parts, or parts displaying deficiencies, will not be accepted and will be returned at the expense of the supplier. A processing fee can be charged to the supplier for non-conforming product.

2.6 Verification of Purchased Product

Stanley Healthcare may at any time reserve the right to inspect product at the supplier's location in the event of suspect material.

Where specified by contract with Stanley Healthcare customers, the supplier must afford Stanley Healthcare's customer the right to access their facilities to verify purchased product. Such verification by Stanley Healthcare's customer neither absolves the supplier of providing acceptable product nor precludes subsequent rejection by Stanley Healthcare's customer.

2.7 Preventive / Continuous Improvement Process Activities

The supplier shall establish and maintain documented procedures for a system of preventive measures. Programs to improve operational areas as well as commercial and technical functional areas are to be implemented and maintained in the supplier company. The system serves to locate and document any potential faults. Appropriate measures will be taken in order to reduce the degree of risk and extent of these potential sources of deficiency. Proof of the effectiveness of these measures is to be furnished by the supplier.

- Instruments recommended for this purpose include:
- Risk Analysis
- FMEA
- Statistical planning of trials / design of experiments
- Examination of test and measuring capability
- Investigation of process capability
- Supplier assessment
- Problem solving techniques
- Benchmarking

The economical use of resources is to be taken into account in the continuous improvements process (CIP). CIP is a continuous activity designed to achieve cost reductions along with improvements in quality and processes.

2.8 Quality Planning

2.8.1 Quality Pre-Planning

During the development and planning period, quality pre-planning activities shall take place between representatives of Stanley Healthcare and the supplier. Such activities may be initiated by Stanley Healthcare upon prior agreement with the supplier.

Quality pre-planning activities shall include any of the following as required by the project:

Feasibility / capacity analysis
Design process FMEA
Drawings / design records
Test equipment planning / coordination
Logistics

Initial sample test
Product qualification (First Article)
Incoming inspection at Stanley Healthcare
Environmental issues

2.8.2 Initial Sample Submission

The purpose of the sample submission is to assure that all Stanley Healthcare design records and specification requirements are fully understood by the supplier and that the process is capable of producing products meeting these requirements during an actual production run.

2.9 Production Quality Requirements

2.9.1 Process Control

Sound and suitable processes lay a quality foundation for our supplied parts. These processes are to be verified through suitable tests which can be authenticated. The characteristics of quality appearing in the technical documentation are to be guaranteed using the appropriate tests. Mass production may not be started until the first article samples have been approved. The supplier shall monitor the processes influencing the primary features (shape, dimensions, function, and safety) of the product.

2.9.2 Electrostatic Discharge Damage Prevention

Suppliers scheduled to provide ESD sensitive devices to Stanley Healthcare shall, prior to processing product, establish, document and implement an Electrostatic Discharge (ESD) Control Program plan in compliance with the requirements of ANSI 2020, or equivalent.

2.9.3 Housekeeping

Production areas must be maintained to ensure that the product is free from burrs, loose items, and foreign objects/debris. Housekeeping practices such as 5S and Clean As You Go are preferred practices.

2.9.4 Environmental Control and Material Handling

The supplier is responsible for ensuring material is stored in the proper environmental conditions to preserve and prevent damage or premature expiration. Additionally, the supplier is required to use inventory assessment practices that ensure materials are protected from loss, damage, expiration, or other deterioration.

2.9.5 Process Capability

Stanley Healthcare is required to furnish proof of process capability for features relating to safety or important to the function. For parameters that are significant to the safety and function of the products, the supplier is required to maintain documented proof of process capability and make it accessible to Stanley Healthcare. The indices for machine and process capability (Cpk) may, at no time, be lower than what had been adopted during product verification process (Cpk > 1.33).

2.9.6 Change Management

The supplier is obligated to inform Stanley Healthcare, in writing, of any planned modifications to its quality assurance system or procedures, including alterations to manufacturing procedures, supplied parts, data sheets or other documents. Information regarding any such modifications must be provided in its totality to Stanley **prior to implementing change** so that Stanley Healthcare can determine whether the changes may affect the quality of a finished device.

For facility moves, Stanley Healthcare requests notification 12 months prior to the move. For all other changes such as equipment or production line changes, suppliers are expected to request the proposed change 180 days in advance of implementing the change. For material or process method changes, suppliers are expected to provide the proposed change as early as possible to allow for additional testing and requalification of product and shall not be implemented without approval from Stanley Healthcare.

Please be sure to notify Stanley Healthcare as early as possible of the potential changes to avoid delays in production schedules. Supporting data may be requested of the supplier to facilitate acceptance of the proposed change.

The Change Control process is initiated by answering these five questions:

1. What is the intended change? (i.e. Changing _____ from _____ to _____)
2. What is the potential impact on product?
3. What is the proposed timing of the change?
4. What supporting data is available? If no data is required, what is the justification?
5. What is the impact if the change is rejected?

2.9.7 Documentation

The documentation on testing procedures is to be maintained in such a way that the supplier can use them to provide consistent proof that the specifications were filled for the duration of the manufacturing process, and that this can be substantiated by test results.

2.9.8 Quality Records Retention and Disclosure

The supplier is required to disclose (for reading only) all quality records upon request.

Systematic Failure reports.

External ISO quality audits.

Internal audits plans and results.

In process production: QC records, inspection results and testing results.

MRB reports.

Failure Analysis.

Quality reports and corrective action plans.

Functional Test results.

Corrective actions report according to 8D method & status.

Production flow status- by request for specific units.

Record retention for quality records is required for a minimum of 5 years. Electronic records shall not be deleted without Stanley Healthcare's prior approval.

2.10 Inspection Requirements

2.10.1 Calibration Program

Test equipment shall be calibrated and traceable according to international standards. The calibration labs shall be ISO 17025 compliant. Calibration reports shall meet the ISO 17025 requirements and shall be available upon request.

2.10.2 First Articles/Qualifications

First Articles inspections are used to demonstrate that a supplier is capable of consistently meeting specifications. First articles are required from suppliers for new product qualification. When applicable, suppliers are required to submit First Article inspections in accordance to Stanley Healthcare's instruction. A copy of the First Article Inspection Report, associated drawings and all special process and finish certifications of all lower level detail parts must accompany the first shipment of unit/assemblies.

2.10.3 Supplier Testing and Data Collection Requirements

In many cases, Suppliers collect qualification data. Supplier-generated data must be produced on calibrated and controlled equipment. The following must be provided to Stanley Healthcare upon request or available for review at the Supplier's facility:

1. Test data
2. Person who conducted the test
3. Test date
4. Test equipment used (i.e. equipment number)
5. Identification of actual test articles: lot number, serial numbers, sample numbers, date code, raw material lot number

2.10.4 Source Inspection

Any work carried out by the supplier may be subjected to tests and inspection of Stanley Healthcare quality control in the contractor's or Stanley Healthcare premises.

Any part of the product manufactured for the main supplier by sub-contractors, or any of its subsidiaries, shall be subject to final inspection and approval of the main supplier or Stanley Healthcare. It is understood that despite any inspection carried out by Stanley Healthcare, the workmanship, material and conformity of any of the parts is the sole responsibility of the main supplier.

Stanley Healthcare is privileged to decide to either perform sample tests or 100% tests. The supplier shall set up space and allow Stanley Healthcare Q.C. representatives the use of equipment at any time. Remark for agreement:

1. Prior notice for audit (3 working days).
2. Acceptance 10 working days.

Source inspection may be done using services of a third party for the performance of Q.C. tests, including representatives of Stanley Healthcare customers. In such a case, the terms mentioned herein apply and the test results shall be sent by the supplier to Stanley Healthcare.

2.10.5 Certificate of Compliance

The supplier shall attach a certificate of compliance (COC) with each shipment stating that the parts, materials, processes and testing furnished by Stanley Healthcare are in accordance with applicable requirements of the Purchase Order. The certificate shall state that the supplier has on file all available data for examination and evidence of conformance to applicable specifications.

2.10.6 Final QC

The supplier's Q.C. is required to perform appropriate sample tests as defined during product development and or Stanley Healthcare product requirements.

Stanley Healthcare reserves the right to request higher level of inspection as result of poor field feedback.

Stanley Healthcare reserves the right to keep a QC inspector at supplier's site.

2.10.7 Traceability

For all parts, materials, and assemblies with traceability identification such as serial numbers, lot numbers, and date codes, the supplier shall maintain the traceability data from procurement through fabrication, assembly, test and delivery. This traceability provides for the ready identification of suspect lots should an individual item be found to be discrepant.

2.11 Logistics

2.11.1 Demands on Suppliers

The supplier must meet Stanley Healthcare's lot quantity requirements and ship the product in the exact amount as scheduled in the purchase order. Where necessary partial shipments may be allowed however they must be approved by the Stanley Healthcare buyer.

2.11.2 Notification / Processing of Demand

The supplier's reaction to changes in orders must be quick and flexible and the supplier must be able to process orders at short notice. Electronic means of communication are necessary for this.

2.11.3 Preventing Delivery Problems

Purchase orders received from Stanley Healthcare must be checked immediately regarding quantities and dates. If difficulties with deliveries or other unforeseen events occur, the supplier must inform Stanley Healthcare immediately.

To ensure supply, especially in critical situations, the supplier must immediately correct the situation and document it.

2.11.4 Flexibility of Fluctuations in Demand

Capacity planning will be agreed upon in conjunction with the supplier. Demand fluctuation will be defined. The supplier must guarantee 100% on-time delivery. Should there be additional demand fluctuations, there must be a capacity adjustment agreement with the supplier.

2.11.5 Packaging & Marking

The definition of packaging is based on the requirements of the packaging system at Stanley Healthcare. The selection of packaging begins before the order is placed and is dependent on placing technical and logistical requirements, as well as on the economy. Packaging must be agreed upon with Stanley Healthcare.

2.11.6 Availability of Goods Information

The delivery notice and transport data must be sent to Stanley Healthcare in advance in order to check the availability of the goods before they arrive when required. Delivery between Stanley Healthcare and the supplier has to be a common logistics concept.

2.11.7 Planning & Agreement

The logistics supply process will be planned by both Stanley Healthcare and the supplier. Results will be recorded in an agreement with the supplier.

2.11.8 Holding production and Shipment

Stanley Healthcare may, at their own discretion, instruct a temporarily halt of production and/ or shipment. This decision shall be sent in an email to the contact personnel in both sides and include the technical reason and estimated interval, or halt termination condition.

The supplier shall act according to the instruction immediately upon receipt and act promptly and in a determined manner to perform the instruction while avoiding continuation of production.

2.12. Contingency Planning

Continuous supply of product is critical even in an emergency situation. To ensure consistent delivery, Stanley Healthcare requests a formal copy of the supplier's contingency plan. Stanley Healthcare will work with a supplier to identify any areas of risk as well as develop alternate plans.

2.12.1 Purpose of Contingency Plan

The purpose of the contingency plan is to have a plan or a procedure that will take effect if an emergency occurs or if an existing situation changes. The plan details procedures for responding to an emergency situation such as fire, tornado, hurricane, in climate weather, work stoppage, etc. Any situation which affects Stanley Healthcare's ability to provide continuous delivery and service to its customers needs to be covered by the contingency plan. If a union facility, a Strike Protection Plan needs to be included in the contingency plan.

3. Acknowledgement and Acceptance

3.1 Quality System Acknowledgement

As a supplier of Stanley Healthcare, we recognize the importance of having a formal quality system compliant to ISO 13485:(Current Revision) Medical Devices and/or ISO 9001(Current Revision).

☐ As such, we currently have a certified/compliant ISO 9001 quality system and have provided Stanley Healthcare with evidence, such as certifications, audit reports, etc.

☐ As such, we are in the process of developing a compliant quality system and have provided a development plan to Stanley Healthcare.

_____ _____ _____
Signature and Title Date

3.2 Change Management Acknowledgement

As a supplier of Stanley Healthcare, we recognize the importance of requesting approval from Stanley Healthcare prior to implementing any changes. We have reviewed section *2.9.6 Change Management* of this Supplier Requirements Handbook and agree that we will provide Stanley Healthcare with 12 months prior to facility moves, and 180 days of other change efforts to review and determine impact to products.

_____ _____ _____
Signature and Title Date

3.3 Supplier Requirements Agreement

As a supplier of Stanley Healthcare, we recognize the importance of the requirements with the Supplier Requirements Handbook. We have reviewed these requirements and agree to comply with the requirements set forth by Stanley Healthcare. In any event where we are unable to comply, we will notify our Stanley Healthcare Buyer for guidance.

_____ _____ _____
Signature and Title Date

Appendix A

Restricted Materials for Stanley Healthcare medical devices or components.

1. Latex
2. DEHP, including:
    a. Bis (2- ethylhexyl) phthalate (DEHP)
    b. Butyl benzyl phthalate (BBP)
    c. Dibutyl phthalate (DBP)
    d. Diisobutyl Phthalate (DIBP)
3. Nickel

Restricted Materials Confirmation

As a supplier of Stanley Healthcare, we recognize the importance of the Restricted Materials which must be absent from all medical devices. We have reviewed these requirements and confirm that the restricted materials listed are not included in any medical device or component we provide to Stanley Healthcare. In any event where we are unable to confirm, we will notify our Stanley Healthcare Buyer for guidance.

_____ _____ _____

Signature and Title Date