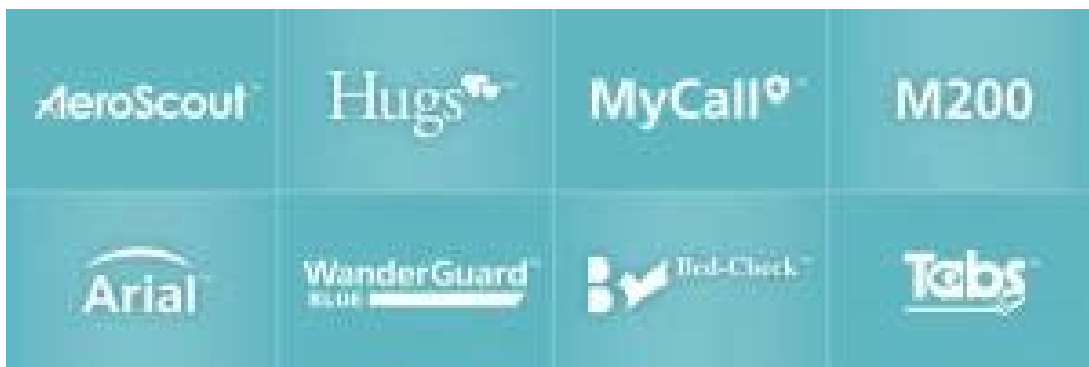


# Supplier Quality and Excellence Handbook

**By Your Side™**  
LIFETIME CUSTOMER CARE

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# 1.0 Introduction

## 1.1 About STANLEY Healthcare

STANLEY Healthcare is a recognized leader in visibility and analytics solutions that transform safety, security and operational efficiency for senior living organizations, hospitals and health systems.

STANLEY Healthcare is an operating division of STANLEY Black & Decker, a Fortune 500 company with a track record of innovation and sustained profitable growths.

## 1.2 STANLEY Healthcare Product Offerings

STANLEY Healthcare product offerings are focused in five critical areas: 1) Security and Protection, 2) Patient and Resident Safety, 3) Clinical Operations and Workflow, 4) Environmental Monitoring, and 5) Asset Management.

STANLEY Healthcare has product offerings that are both FDA Medical Device listed, and non-FDA listed. FDA listed product lines require compliance to FDA regulatory requirements codified in 21 CFR Part 820 or embodied in ISO 13485/ISO 9001. As such STANLEY Healthcare practices cGMP/ISO 13485/ISO 9001 and has quality system certifications for these standards.

## 1.3 Purpose and Scope

The purpose of this Supplier Handbook is to communicate STANLEY Healthcare's quality requirements and expectations to all new and

existing suppliers. This document was developed as a baseline for qualifying new suppliers and supporting our existing suppliers in understanding and upholding STANLEY Healthcare's requirements and expectations.

The requirements and expectations included in this document apply to each stage related to the development, manufacture, delivery, and support of all products or services provided to STANLEY Healthcare. This Handbook serves as a supplement and does not take precedence, nor serves as a replacement for pre-established agreements, engineering specifications, or STANLEY Healthcare purchase orders.

We recognize that STANLEY Healthcare has a wide-range of suppliers with varying technologies and capabilities; the expectations stated in this manual may apply in different ways, depending on the Product or Service supplied.

## 1.4 Non-Disclosure Agreement

STANLEY Healthcare may ask a Supplier to sign a Non-Disclosure Agreement in certain cases where proprietary information is shared throughout the course of business with a Supplier. STANLEY Healthcare utilizes a standard Mutual Confidentiality Agreement form for this purpose.



## 2.0 Sustainability and Environmental Responsibility

### 2.1 Regulatory Compliance

Suppliers must fully understand and comply with all country and local environmental regulations for the areas in which they operate.

In addition to STANLEY Healthcare employees, we expect all of STANLEY Healthcare partners, distributors, resellers, advisors, consultants, contractors, agents and other intermediaries representing STANLEY Healthcare to adhere to the dictates contained in our Code of Business Ethics and Human Rights Policy Statement.

More information on Corporate Social responsibility is available on STANLEY Black and Decker website (See Appendix A: Resource Links).

### 2.2 RoHS Compliance, REACH, WEEE, Conflict Minerals

Suppliers are expected to state RoHS, REACH, WEEE, and/or Conflict Mineral compliance on the Declaration of Compliance with each purchase order.

Restricted substances for suppliers must be declared per ES100118 Engineering Specification & Form for Restricted Substance Declaration (See Appendix A: Resource Links).

### 2.3 Regulated Substances

Suppliers must fully understand current legislation on global material restriction.

Suppliers are expected to have adequate systems in place designed to identify and disclose to STANLEY Healthcare all material content of an approved part, sub-component, sourced product, accessory, and packaging to ensure that the requirements of the STANLEY Black and Decker Controlled Substances Standard specifications are fully met.

Suppliers should be aware of how their businesses and Products impact the environment and the safety/health of employees.

Suppliers should commit to continuous environmental, safety and health improvement, including the lowering of the supplier's carbon footprint.

Notify STANLEY Healthcare of any significant environmental compliance violations.

Provide composition information on parts/components as requested where necessary.

#### **Materials of Special Interest to STANLEY Healthcare**

Restricted Materials for STANLEY Healthcare generally include:

- Latex.
- DEHP, including: Bis (2- ethylhexyl) phthalate (DEHP); Butyl benzyl phthalate (BBP); Dibutyl phthalate (DBP); Diisobutyl Phthalate (DIBP).
- Nickel (Exceptions include populated circuit boards with Electroless nickel Immersion Gold (ENIG) surface finishes).

Restricted materials will be defined in product requirements per project scope with the supplier.

### 2.4 Business Continuity

Continuous supply of product is critical even in an emergency. To ensure consistent delivery, suppliers are expected to submit a formal copy of their contingency plan. STANLEY Healthcare will work with supplier to identify any areas of risk and develop alternate plans.

## 3.0 Business Management System

### 3.1 Quality Management System

Suppliers to STANLEY Healthcare must have an established and documented Quality System that includes all appropriate elements of a quality system best suited for the supplier's business management system.

The management system shall be designed to ensure: (a) compliance with Supplier Standard Operating Procedures and customer requirements related to the supplier's operations, products and services; (b) conformance with an International standard of organization quality systems (i.e. ISO 9001 or ISO 13485) or cGMP; (c) identification and mitigation of risks related to products or services provided to STANLEY Healthcare; (d) the facilitation of corrective/preventive action and continuous improvement.

When a supplier is part of a STANLEY Healthcare FDA medical device listed product supply chain, Quality System certifications may be necessary to ensure compliance to 21 CFR Part 820 as embodied in ISO 13485/ISO 9001.

### 3.2 Change Management

Suppliers are required to notify STANLEY Healthcare of changes made to materials, products, or processes. This should include facility changes and/or changes associated with sub-tier suppliers.

Suppliers must notify STANLEY Healthcare **prior** to implementing such changes by submitting a STANLEY Healthcare Change Management Form (See Appendix B). It is STANLEY Healthcare's responsibility to determine whether the changes could affect the quality of a finished device.

### 3.3 Audit and Assessment

To ensure compliance to STANLEY Healthcare's Quality Requirements, suppliers must allow STANLEY Healthcare Personnel and Regulatory Authorities to audit and have access to the supplier or sub-tier supplier's processes, quality systems, and facilities.

Suppliers are expected to provide a prompt response for all audit findings.

For STANLEY Healthcare's medical device manufacturers, unannounced audits may be performed by Notified Bodies. Notified Bodies (NB), which ensure the safety of medical devices sold in the European Union (EU) Member States, conduct unannounced audits of medical device manufacturers. Unannounced audits by a Notified Body (NB) may also be performed at STANLEY Healthcare's critical contract manufacturers or crucial suppliers involved with producing STANLEY Healthcare products sold in the EU.

### 3.4 Sub-Supplier Control and Flow Down

STANLEY Healthcare suppliers must have a documented supplier management system for managing their suppliers. The supplier management system should include appropriate QMS requirements, quality assurance practices, and quality control methodologies.

STANLEY Healthcare suppliers may be required to flow down quality requirements to their sub-tier suppliers. Suppliers are expected to monitor and measure compliance from sub-tier suppliers.

## 4.0 Quality Assurance

### 4.1 Qualification and Requalification

All new suppliers for STANLEY Healthcare are required to complete STANLEY Healthcare's supplier qualification process. Supplier Qualification process may include: Procurement Agreements, Supplier Self-Assessments, Audits, and potential Statement of Work Agreements.

Existing suppliers for STANLEY Healthcare may be required to complete the STANLEY Healthcare requalification process which includes the review of various agreements, supplier performance, and continuous improvement. On-site audits may be conducted during requalification.

### 4.2 Quality Assurance Methodologies

STANLEY Healthcare expectations for quality assurance includes utilization of measurement systems and analysis (MSA), process capability studies (CP, CPK, PP, PPK), control plans, pFMEAs, and cost of poor quality (COPQ).

Supplier Quality Control procedures must ensure personnel are trained and competent to perform defined inspection and test methods.

### 4.3 First Articles

Suppliers are required to provide STANLEY Healthcare First Articles submissions for new product qualification and any changes made during the product lifecycle.

First Articles inspections are used to demonstrate that all STANLEY Healthcare design and specification requirements are fully understood by the supplier and that the process is capable of producing products that meet these requirements during an actual production run.

### 4.4 Escapes

Suppliers are required to immediately notify STANLEY Healthcare in the event where products have been released by the supplier or sub-supplier and are subsequently determined to be nonconforming.

### 4.5 Supplier Corrective Actions

Suppliers are expected to fully cooperate with STANLEY Healthcare's investigation and containment actions per STANLEY Healthcare's Supplier Corrective Action Procedure (Appendix C).



## 5.0 Supplier Performance

### 5.1 On-Time Delivery

Suppliers are expected to deliver all orders to STANLEY Healthcare on the required date agreed upon with each purchase order.

STANLEY Healthcare utilizes a working day calendar where exclusions are made for holidays and weekends associated with the country of purchase order origin. Typically, deliveries are considered on-time when they are delivered within a four-day window of the required date of the purchase order. The four-day window includes shipments delivered two days before, one day after, and including the required date of the purchase order.

### 5.2 PPM/Cost of Poor Quality

STANLEY Healthcare will notify suppliers of nonconforming product in the event a supplier nonconformance report is raised. Suppliers are expected to provide immediate support to prevent disruption of STANLEY Healthcare production. Disposition of nonconforming product may include returning the nonconforming

material for a replacement, repair, or a credit. However, suppliers are expected to cover freight costs related to the disposition decision. STANLEY Healthcare may be willing to dispose of nonconforming product locally upon supplier authorization.

### 5.3 Scorecards

STANLEY Healthcare's Supplier Performance Scorecard will measure supplier performance on a periodic basis. Supplier performance data will be collected and used for periodic supplier business reviews and decision making in the continuation, extension, or termination of supply.

### 5.4 Annual Surveys

STANLEY Healthcare conducts internal Supplier Surveys on an annual basis with the purpose of capturing internal employee's opinion of their interactions with our suppliers throughout the year. The surveys measure support aspects such as, Communication & Responsiveness, Customer Support, Reliability, and Supply Chain Support.

| Supplier Status Levels   |   |   |   |
|--|---|---|---|
| <b>Not Approved</b><br>Supplier is in the qualification process and not approved for production purchase orders. | <b>Approved</b><br>Qualification process completed.<br>Procurement and Quality Agreements have been negotiated and agreed upon.<br>Product has initially proven to meet product requirements.<br>Incoming Inspection may still be required. | <b>Preferred</b><br>Procurement and Quality Agreements are being fulfilled as agreed.<br><br>KPI metrics (PPM, OTD, Cost) are at acceptable levels.<br><br>Product is accepted on dock-to stock status. | <b>Certified</b><br>Procurement and Quality Agreements are reliably fulfilled.<br><br>KPI metrics (PPM, OTD, Cost) are consistently achieved or exceeded.<br><br>Product is accepted on dock-to stock or drop shipped status. |

**Please Note:** Acceptance of a STANLEY Healthcare purchase order (PO) constitutes acknowledgment that the Supplier has read and understands the expectations of this Manual.



# Appendix A: Resource Links

## About STANLEY Healthcare

For more information regarding STANLEY Healthcare and its Solutions, Services, Partners, Technology, Company Information. Please visit the website at: [www.stanleyhealthcare.com](http://www.stanleyhealthcare.com).

## Stanley Black and Decker

Stanley Black & Decker is committed to setting strategic targets and adhering to policies and arrangements that support human rights, equality and environmental sustainability.

Stanley Black and Decker Resources and Policies are located here:

[www.stanleyblackanddecker.com/social-responsibility/resources-policies](http://www.stanleyblackanddecker.com/social-responsibility/resources-policies)

## Stanley Black and Decker Quick Links for Suppliers:

[Corporate Social Responsibility](#)

[Code of Business Ethics](#)

[Human Rights Policy Statement](#)

[Restricted Substances-ES100118](#)

[Terms and Conditions](#)

## STANLEY Healthcare Supplier Management

STANLEY Healthcare forms for suppliers are available on Stanley Black and Decker's Global Supplier Portal website: <https://gsp.sbdinc.com>. No log in required, simply click on the "Public Tab" in the center, select "Department Information" and then "Healthcare" from the drop-down menu. An array of options will appear to the right.

## STANLEY Healthcare Quick Links:

[Supplier Quality and Excellence Handbook](#)

[Supplier Self-Assessment Form](#)

[Supplier Change Request Form](#)

[Supplier Performance Scorecard](#)

[Supplier First Article Inspection-General](#)

[Supplier First Article Inspection -PCB](#)

[Supplier Annual Self-Assessment](#)



## Appendix B: Supplier Corrective Action Process

### Supplier Corrective Action Overview

When deemed appropriate, STANLEY Healthcare will issue a Supplier Corrective Action Request (SCAR) form. Suppliers may use STANLEY Healthcare provided SCAR form or their own 8D CAPA form.

Please note STANLEY Healthcare's definitions of stages, activity per stage, and anticipated timeline per activity are listed below.

STANLEY Healthcare recognizes that the timeline will vary per situation, so please keep your STANLEY Healthcare Representative updated.

| Stage   | Activity   | Timeline |
|---|--|----------|
| Acknowledge & Contain                                 | Supplier acknowledges receipt of assignment of CA and contains suspect product within the supply chain.  | 24 Hrs.  |
| Root Cause and Interim CA/PA Plan                     | Supplier has reviewed nonconforming product to identify disposition and possible rework, use-as-is, scrap, and replacement opportunities.<br>Supplier has conducted a formal root cause and has submitted Corrective and Preventive Action Plan. | 3-5 Days |
| Long Term Corrective Action & Preventive action Plan. | Supplier has identified the long-term corrective action and preventive action plans with implementation dates.   | 7 Days   |
| Implementation & Verification                         | Supplier implements the Corrective and Preventive Actions per plan.  | Per Plan |

Should additional time be required to investigate the root cause or suitable corrective actions, a request for extension may be made. Failure to provide this information could result in disqualification as a supplier source.

Parts deemed unacceptable for use will be returned to the Supplier for evaluation unless the Supplier provides other disposition instructions.

# Appendix C: Supplier Performance Scorecard Overview

## Supplier Performance Scorecard

**Purpose:** STANLEY Healthcare Supplier Performance Scorecard will measure supplier performance on a quarterly basis. Supplier performance data will be collected and used for periodic supplier business reviews and decision making in the following areas:

- Continuation of supply
- Extension of supply (additional business)
- Termination of supply

**Scope:** The scope of the scorecard includes purchased materials, primarily focused on direct materials. One scorecard per supplier will be generated\* encompassing all parts procured on a quarterly basis.

*\*STANLEY Healthcare reviews supplier performance and determines which supplier will receive a scorecard on an annual basis. Selection is dependent on regulatory requirements of product procured, previous supplier performance, current level of spend with supplier and criticality of purchased product within STANLEY product or system designs*

| Scorecard Categories                    | Points | Weight     |
|---|--------|------------|
| <b>Quality</b>                          |        | <b>60</b>  |
| Defective PPM                           | 20     |            |
| SCARs - Count                           | 15     |            |
| SCAR Response Time                      | 15     |            |
| Supplier Nonconformance Reports - Count | 5      |            |
| SNCR Response Time                      | 5      |            |
| <b>On-Time Delivery</b>                 |        | <b>40</b>  |
| On-Time Percentage                      | 40     |            |
| <b>Total Points</b>                     |        | <b>100</b> |

| Overall Performance Ratings |                             |
|-----------------------------|-----------------------------|
| Score Range                 | Rating                      |
| 89-100                      | Exceeding Expectations      |
| 79-88                       | Meeting Expectations        |
| 69-78                       | Needs Improvement           |
| <68                         | Improvement Action Required |

### Quality - Includes Three Parts:

1. Defective Parts Per Million (DPPM)
2. Count of Supplier Corrective Action Requests (SCARs) initiated during the current scorecard period.
3. Count of Supplier Nonconformance Reports (SNCRs) initiated during the current scorecard period.

### On Time Delivery - Includes One Part:

1. Percentage of on-time deliveries per purchase order line within scorecard period.