

SUPPLIER HANDBOOK



Supplier Handbook

INTRODUCTION

CONMED Quality Policy

At CONMED our passion and responsibility is for the success of our customers and the patients for whom they care.

We empower our customers to succeed by our commitment to integrity, quality, responsiveness and a relentless focus to deliver accessible CONMED solutions. Our talented employees and culture are the foundation of our success.

Our Mission

Our Mission is to enable healthcare providers around the world to deliver exceptional outcomes for patients, through accessible CONMED solutions.

CONMED Corporation (NYSE:CNMD)

CONMED's exciting history began in 1970, when we were first established by Eugene Corasanti in Utica, New York as Consolidated Medical Equipment, Inc. The company's first product was the disposable ECG monitoring electrode. The electrode market was booming as disposable products began to rapidly gain acceptance. This began our growth streak in the medical device industry and we have been expanding ever since.

Today, CONMED manufactures and markets thousands of products to providers across the healthcare continuum. We are a leader in Orthopedics, General Surgery, Gynecology, Gastroenterology, Laparoscopy, Cardiology and Critical Care markets. We continue to offer innovation and value added customer service across all our product lines.

With multiple manufacturing and design facilities, over 3,500 employees, and worldwide distribution, CONMED strives to improve the quality of healthcare by designing, producing and marketing innovative, high-quality products.

Preferred Supplier Program

CONMED Corporation offers a preferred supplier program whereby companies that meet quality, delivery, and cost performance requirements, align with the strategic needs of the business and support competitive commercial terms are selected as a targeted partner for CONMED's global supply base consolidation efforts and product development initiatives. Preferred suppliers gain access to CONMED's business units and introduction to other business development opportunities as a result of their performance. Preferred suppliers are also targeted for participation in business across multiple technical and operational disciplines.



Purpose

This hand book has been developed as a reference document for our suppliers of material and services, and provides an overview of CONMED's approach to Global Supplier Quality Management and requirements for suppliers. This document describes not only best practices but expectations of our suppliers with whom we choose to develop long term partnerships. Please share this with your team members and retain it as an important reference document.

Supplier Management Overview

CONMED's global supply chain management team consists of dedicated specialists in strategic sourcing, commodity management, procurement, and supplier quality engineering. Our team has invested significant effort into the development of our Supplier Quality Management process which provides a structured framework for the control of supplied product intended for use in our heavily regulated medical device industry.





SUPPLIER EXPECTATIONS AND REQUIREMENTS

Quality Management System Expectations

CONMED Corporation expects its supplier chain partners to have an effective and well-documented Quality Management System (QMS). Suppliers must have Current Good Manufacturing Practice (cGMP) as stated in Title 21 of the Code of Federal Regulations, Part 820, to be followed and practiced. Formal registration with a notified body, for example ISO 9001, ISO 13485, or equivalent is required unless formally waived.

Suppliers must have a documented Quality Management System per cGMP	Requirement
Suppliers should maintain an industry standard certificate, eg. ISO 9001 or ISO 13485	As Applicable

Because each CONMED facility has unique customer requirements, individual CONMED facilities may establish additional quality expectations. At a minimum, a CONMED supplier will establish, document, implement, maintain, and continuously improve the effectiveness of their quality management system. Please feel free to discuss this hand book and any quality expectations with your specific CONMED facility's quality and procurement representatives.

Suppliers will have a documented continuous improvement process	Expectation
Suppliers should utilize industry standard continuous improvement programs (eg. Six-Sigma DMAIC, Lean Six-Sigma)	Best Practice

Suppliers are expected to complete a self-evaluation to identify and resolve deficiencies to the requirements in this guidebook. The supplier shall also consider and evaluate your own supply chain. Your CONMED supplier quality representative can assist you with any questions you may have in completing the evaluation.

Supplier Code of Conduct

CONMED Corporation is committed to operating its business in an ethical and legal manner and we expect our Suppliers also shall ensure their operations are being performed in a manner that is ethical, legal, environmentally, and socially responsible. CONMED's Supplier Code of Conduct is intended to communicate these expectations. In addition to any specific requirements in our written agreements, we expect our Suppliers to comply with this Code and any future amendments. Below is a listing of the basic requirements:

- **Compliance with Local Laws and Regulations**
Suppliers must adhere to the laws and regulations in the locality in which they reside. This includes all local, state, and federal laws/regulations in the country of origin.



- **Compliance with Environmental, Health, and Safety Laws**
The Supplier must maintain and operate its manufacturing/production facilities and processes in accordance with local, state, and federal laws/regulations in the country of origin.

At no time shall any CONMED employee or representative be exposed to hazardous materials or unsafe conditions as a result of Supplier shipments to a CONMED location, or while visiting a Supplier's location. For items with inherent hazards, safety notices must be clearly visible. As applicable, documented safety handling and protection information must be provided.

- **Product Safety**

In all instances where a product is manufactured to a new design, for a new system, or for a new application, it is important that the Supplier and CONMED allocate responsibility for assuring that all complaint, performance, endurance, maintenance, safety and warning requirements are met. It is *required* that this allocation of responsibility be in writing.

- **Non-Discrimination**

Suppliers shall not discriminate against race, color, sex, religion, age, physical disability, political affiliation, or other defining characteristics as prohibited by local, state, and federal laws/regulations in the country of origin.

- **Child Labor**

Suppliers shall employ workers of minimum legal age in accordance with local, state, and federal laws/regulations in the country of origin. Child labor laws must be followed, but in no event shall a Supplier employ workers under the age of 16.

- **Human Rights & Labor Standards**

CONMED Corporation, together with all of its subsidiaries (collectively, "CONMED"), is committed to the respect of human rights and upholding labor standards. This Human Rights and Labor Standards Policy is aligned with the principles established within the Universal Declaration of Human Rights and in combination with CONMED's Mission Statement and Vision Statement, and reinforces the commitment to ensuring all internal and external stakeholders are treated with dignity and respect. As part of due diligence when entering into acquisitions, new operations and other contractual arrangements, CONMED seeks to abide by the requirements set out in this Policy to ensure any labor standards and human rights issues are identified and assessed.

Likewise, our human rights and labor standards shall be incorporated into our Supplier Code of Conduct, which shall include an audit program which will seek to document compliance with suppliers' performance with respect to human rights compliance (including human trafficking, labor conditions and slavery). This entity level or company-wide Policy does not override specific policies, procedures, laws or regulations in the local jurisdictions, but instead serves to complement them. As noted above as a supplier and business partner to CONMED you are expected to abide by this policy. If there is a conflict between this Policy and a specific local policy, procedure, law or regulation, then this conflict should be referred to CONMED's General Counsel at corporate headquarters. Please visit: <https://www.conmed.com/en/about-us/investors/corporate-governance> for more information on this policy and other ESG related topics.

- **Ethics**

Evidence of corruption, bribes, improper advantage, or any other form of illegal practice by the Supplier or associated operations will terminate all relations with CONMED. Suppliers will conduct their business in a manner that meets the 'Code of Business Conduct and Ethics' policy of the CONMED Corporation. Please visit: <http://www.conmed.com/en/about-us/company/code-of-business-conduct-and-ethics> for more information.



- **Code of Business Conduct and Ethics, and Policy Enforcement**
This policy applies to Suppliers and their sub-tier sources. It is the responsibility of the Supplier to verify and monitor compliance of this code at their operations and sub-tier source operations
- **Confidentiality**
The Supplier shall ensure the confidentiality of CONMED products and projects under development, and related product information, as well as intellectual property shared as a result of the working relationship.

Contractual Requirements

CONMED Corporation includes terms and conditions on all purchase orders. Acceptance of a CONMED purchase order constitutes acceptance of the requirements of the purchase order terms and conditions. In addition to the requirements contained in the purchase order, CONMED will execute a Supplier Quality Agreement and, where applicable, a Regulatory Agreement. A Supplier Quality Agreement is a specific type of contract which defines terms and conditions that include responsibilities for quality. A Supplier Quality agreement is a legally binding contract under which the supplier and CONMED Corporation will conduct business. Suppliers are expected to understand these requirements and discuss them with your CONMED representative to make effective business decisions.

Proprietary & Confidential Information

All suppliers, including sub-tier suppliers, shall consider all CONMED engineering drawings and documents, electronic or otherwise, related to requests for quotes and purchase orders, as CONMED's proprietary information. This may include drawings, specifications, software, samples parts, and sketches. All such items shall remain the property of CONMED Corporation. When suited to the level of engagement, suppliers will be required to sign a Non-Disclosure Agreement (NDA).

Communication

Communication between CONMED and our suppliers is vital to our successful relationship. All parties must be willing to collaborate at all levels. While most discussions will include cross-functional representations from both sides, it is expected that any communication regarding CONMED products will include either a procurement or supplier quality representative from CONMED. While many discussions will take place throughout the supplier-CONMED relationship, suppliers shall not make changes to specifications without written approval from a duly authorized CONMED representative to do so.

Business Continuity Plan

The Supplier should have a business continuity plan which would allow for the safeguarding, storage and recovery of engineering drawings, electronic media, and production tooling in the event of damage or loss. This plan should also contain contingency plans to satisfy CONMED requirements in the event of significant utility disruptions, labor



shortages, equipment failure and field returns. The Supplier should have a succession plan to preclude disruption in production, quality or delivery as a result of upset or change in management or organizational structure.

Notification of Change

Suppliers shall not make any changes to specification, process, material, or requirements for supplied product without notifying the appropriate CONMED representative in advance, and in writing. No changes shall be implemented without obtaining written approval from the appropriate CONMED representative. Unless notified otherwise in writing, the appropriate CONMED representative shall be the CONMED purchasing or procurement agent noted on the affected purchase order. A CONMED supplier quality engineer should also be included on any change communication. Changes requiring notification include, but are not limited to:

- Changes in the manufacturing or service process
- Changes in the material used
- Changes in color
- Changes that can impact the form, fit, or function of the part
- Changes in facility registration status; ISO, FDA, etc.
- Changes in tooling
- Changes in supply chain
- Changes in manufacturing or service location
- Changes in test or inspection process which reduce the sampling rate, or lower the degree of accuracy, or increase the uncertainty of measurement or test results

Suppliers of a PMA Class III device; or suppliers of material, components, services, or processing, that are incorporated into the manufacture of a CONMED PMA Class III device, must provide notification of every single change involved in the item or service provided. 180 days of prior notice is recommended. Such suppliers will be informed, prior to business engagement, that their product, material, or service will be used in a Class III (life sustaining / life supporting) PMA device.

Sub-Tier Supplier Management

Suppliers are expected to maintain qualification parameters for sub-tier suppliers and for the products and materials purchased from them. It is the responsibility of CONMED's supplier to control the quality of the material and components they procure to support the production of products provided to CONMED.

Counterfeit Material or Product

CONMED Corporation prohibits the use of counterfeit material or product. Counterfeit material is a copy or substitute without the legal authority, or whose material, characteristics, or performance is knowingly misrepresented.

Regulated Products and Material

Products and material supplied to CONMED must meet the requirements of country, federal, state, and local environmental regulations. Regulations that restrict the use of certain products, or certain materials obtained from specific regions, include the RoHS Directive, the REACH Regulation, Conflict Minerals (aka: Dodd-Frank Act, section 1502), Waste Electrical and Electronic Equipment (WEEE) and the State of California Proposition 65.



ConMed Corporation has partnered with Assent Compliance to obtain chemical and substance information from supply chain partners to meet various regulatory obligations and the needs of our customers. As a supplier to ConMed you are expected to respond to requests for chemical and substance data that originate from our compliance partner and are legally obligated to provide data that is complete and accurate.

CONMED Owned Property

When necessary, CONMED may entrust Suppliers with CONMED supplied property including tooling, materials, reusable containers, test equipment, software, intellectual property, and other purchased or furnished items. The supplier shall assure such items are identified, protected, verified, and maintained to ensure expected operating performance. Where any such item becomes lost, damaged, or is otherwise found unsuitable, the supplier shall report the information to CONMED. The supplier will not dispose of any CONMED property without prior written approval from CONMED.

SUPPLIER EVALUATION AND SELECTION PROCESS

Process Overview

CONMED Corporation suppliers are selected after a thorough review and evaluation of

- Overall business health (for example, Dun & Bradstreet report)
- Quality Management System, using ISO 9001 or 13485 as the preferred standards
- Approach to service including on time delivery
- Ability to meet CONMED's requirements
- Continuous improvement capabilities
- Strategic alignment and partnering on development projects
- Planning method and inventory policy
- Corrective action and Preventative action processes
- Design & engineering strengths, where applicable
- Verification and/or validation methodology

Supplier Audits

Procurement Audit: Verification that the supplier has adequate financial resources, solid business integrity, and ethics including compliance with the CONMED Code of Conduct. Suppliers are evaluated for financial resources, capacity for growth, ability to meet schedules, experience in the area being evaluated, and cost.

Technical Audit: Evaluation of the supplier's technical expertise and capability to produce the requested material. This may include an evaluation of the manufacturing environment, measurement capability, manufacturing equipment, engineering staff, experience with similar products, and the ability to obtain materials.

Quality Audits: Evaluation of the supplier's quality system through a self-assessment or an On-site audit. This will include a review of the supplier's quality manual, compliance to management reviews, training, currency of quality procedures, control of documentation, verification and validation methods, nonconformance management and correction, process quality controls, and supplier/purchasing controls.



Quality System Expectations

In the absence of third-party certification (eg. ISO 9001 / 13485), depending on the product, its application, value, and criticality, the CONMED Supplier Quality representative may authorize the acceptance of other evidence of compliance. This may include second-party (CONMED) audit or first-party (self) assessment to the applicable criteria above, or to a set of alternative basic quality requirements.

Quality Manual

Upon request, the Supplier shall furnish CONMED with a copy of the Supplier's Quality Manual, which is to be current and approved by the Supplier's management, including or making reference to related documents. The quality management system documentation shall include the Supplier's statements of a quality policy and quality objectives. Top management shall define quality objects and measurements which should address customer expectations and be achievable within a defined period of time. The Supplier shall promptly notify CONMED of any substantive changes to the Supplier's quality management system or personnel.

The Supplier Approval Process may include the following:

Supplier Initial Assessment

CONMED may request the Supplier to provide a copy of its quality management system certificate and/or complete a self-assessment of its business and quality management system and capabilities (i.e., quality, delivery, technology, cost, and continual improvement objectives.)

Documentation Audit

In those cases, where a Supplier's quality management system has not been certified by an accredited certification body, CONMED may request a copy of the Supplier's Quality Manual and supporting procedures (and perhaps internal audit reports) to determine if the Supplier's quality management meets CONMED requirements.

On-Site Assessment

When a Supplier is certified to a related standard by an accredited certification body, CONMED may not conduct an on-site assessment of the Supplier's quality management system against the same criteria. However, CONMED, due to

product/process complexity or criticality, may elect to conduct on-site assessments of a Supplier's product or process capabilities.

New CONMED calibration suppliers are required to either be registered to an ISO Standard (ISO-9001, ISO-13485) and/or accredited to ISO/IEC 17025 (*General Requirements for the Competence of Testing and Calibration Laboratories*). Accreditation ensures the calibration supplier meets the requirements, and is in compliance with, ANSI/NCSL Z540-1. A 'Calibration Supplier' is defined as a non-manufacturing entity that provides NIST (*National Institute of Standards and Technology*) traceable calibration services on a variety of instruments used to verify product or process. The term 'Calibration Supplier' is not to be confused with an OEM manufacturer that returns their own instrument product line to OEM specifications.



GENERAL QUALITY REQUIREMENTS

The following set of general quality requirements applies to all Suppliers.

Compliance to Contractual Requirements

Upon accepting a CONMED contract, the Supplier is responsible for compliance with all contract (e.g., engineering drawing, specification purchase order) requirements. All documents, drawings, and specifications, regardless of origin, are applicable to the Supplier when specified in the contract or documents referenced in the contract, and are required to be used at all levels of the supply chain.

CONMED Designated Sources

Where specified by contract or released engineering print, the Supplier shall purchase products, materials or services from CONMED designated sources. However, the Supplier is responsible to ensure that items procured from such sources meet all applicable technical and quality requirements.

Control of Sub-Tier Suppliers

The Supplier, as the recipient of the contract, is responsible for meeting all requirements, including work performed by the Supplier's sub-tier Suppliers (also known as Sub-Suppliers or subcontract Suppliers.) When the Supplier uses sub-tier sources to perform work on products and/or services scheduled for delivery to CONMED, the Supplier shall include (or flow-down) on contracts, to its sub-tier sources, all of the applicable technical and quality requirements contained in the CONMED contract, including quality system requirements, regulatory requirements, the use of CONMED designated sources, and the requirement to document and control key characteristics and/or key processes and to furnish certifications and test reports as required. CONMED reserves the right-of-entry to sub-tier facilities, subject to advance notice and proprietary considerations.

Product Qualification

This defines the generic requirements for production part qualification and approval. The purpose is to determine if all CONMED design and specification requirements are properly understood by the Supplier and that the manufacturing processes have the capability to consistently meet these requirements. Other considerations include coordinating measurement and inspection tools and techniques to ensure both CONMED and the Supplier part verifications are on equal ground.

First Article Inspection

As a minimum, a First Article Inspection (FAI) is required to initially qualify a part/process for Supplier approval. Furthermore, a new FAI may be requested if there is an extended gap of time since the last production. The FAI



requires that all features and characteristics on the design specification and control plan be inspected and verified prior to production. Actual measured values shall be recorded as opposed to general statements of conformance or other notations simply indicating acceptance.

Supplier Readiness

When required by CONMED, the Supplier shall submit a more comprehensive qualification package, referred to as a Supplier Readiness Package. The extent of this package will be documented on a CONMED Supplier Readiness form and signed by representatives from CONMED and the Supplier. Typical Supplier Readiness

packages may include, but are not limited to, process flow maps, verification and/or validation plans, Measurement System Analysis (MSA), design and/or process FMEA, etc.

Design Records, Change Documents, and Customer Approval

The Supplier shall have the design records for the saleable product, part or component. Any authorized engineering change shall be documented by a released revision change on the engineering print. Red-lines, emails, or other forms of notification of change are not acceptable and are not to be accepted unless accompanied by a copy of a signed Engineering Change Order (ECO) that is stamped "Approved for Production".

Process Flow Diagrams

The Supplier shall have a visual diagram of the proposed or current process. This diagram shall clearly describe the production process steps and sequence, and meet the specified CONMED needs, requirements and expectations.

Failure Mode and Effects Analysis

Suppliers with product design responsibility shall develop a Design FMEA in accordance with, and compliant to, CONMED-specified requirements. A single Design FMEA may be applied to a family of similar parts or materials. Suppliers with process validation responsibility develop a Process FMEA in accordance with, and compliance to, CONMED-specified requirements. Where appropriate, CONMED may require the Supplier to develop a Process FMEA where processes do not require validation but require specific consideration of risk.

Measurement Systems Analysis

The Supplier must develop or obtain gages and standards to control their process and to determine product conformance to specifications. Variable gages and measurements are preferred. Alternative methods, gages or standards may be used. CONMED may request the Supplier to participate in a correlation study to compare Supplier measurement results against results obtained by CONMED gages and methods. Gage studies may include analysis for repeatability, bias, linearity, and stability.

Control Plan

The Supplier shall have a Control Plan that considers the output from the FMEA and defines all methods used for process monitoring and control of special product / process characteristics. A single control plan may apply to a group or family of products that are produced by the same process at the same source.

Process Capability Study

Process Capability Index (Cpk) is a comparison of the inherent variability of a process output to specification limits under statistically stable conditions. Most methods for estimating capability require that the characteristic being evaluated is approximately normal in distribution, and in statistical control. The distribution should be determined prior to estimating capability. If the process is not in statistical control, all assignable causes must first be identified and removed or mitigated. Special techniques are available for calculating capability when inherent assignable



causes, such as tool wear, are present. Cpk expectations may be specified by CONMED on specific contracts or items.

Process Controls

This defines the basic necessities for Suppliers to control their manufacturing processes.

- **Print Requirements**

The Supplier shall demonstrate conformity to those characteristics specified on the CONMED engineering prints through means of documentation and appropriate control methods. In addition, the Supplier shall also review, identify, document and control all other product

and process characteristics that are key to achieving quality.

- **Mistake-Proofing**

The Supplier should use mistake-proofing devices and techniques (sometimes referred to as Poka-Yoke) as a form of process control; especially repetitive functions, difficult tasks prone to mistakes, or where the cost of error is high.

- **Work Instructions**

The Supplier shall prepare and maintain documented work instructions, as necessary, for all employees having responsibilities for the operation of processes that impact CONMED product quality. These instructions shall be maintained current, controlled, and available to each affected employee.

- **Control of Monitoring and Measuring Devices**

The Supplier shall determine the monitoring and measurement to be undertaken and the monitoring and measurement devices needed to provide evidence of conformity to product specifications. As a minimum, where necessary to ensure valid results, measuring equipment shall:

- Be calibrated or verified at specified intervals, or prior to use, against traceable measurement standards.
- Be identified, so as to allow the calibration status to be determined.

- **Preventative Maintenance**

The Supplier should identify key process equipment and provide resources for machine/equipment maintenance activities. An effective planned preventative maintenance system shall exist or be developed.

- **Shelf-Life Control**

The Supplier shall maintain a system that records, monitors and manages special handling, storage requirements, and data control of limited or specified shelf-life materials or products. This shall include lot or batch numbers, cure or manufacture dates, or expiration dates as applicable.

- **Sampled Inspection**

The Supplier is responsible for 100% Verified quality for all items delivered to CONMED. When the Supplier elects to use statistical methods for the acceptance of products or processes, a copy of the statistical process control plan shall be furnished to and approved by CONMED during product qualification.

- **Raw Material Lot Control**

For CONMED, the Supplier shall ensure and maintain records of positive traceability for each individual product, lot, or batch to the raw material level. CONMED may specify which products require this documentation be sent with each receipt, for all others records must be maintained and provided upon request.

- **Electro-Static Discharge (ESD) Control**

Suppliers contracted to provide ESD sensitive devices or assemblies to CONMED shall establish, document, and implement an Electrostatic Discharge (ESD) Control program in compliance with the requirements of MIL-STD-1686 or equivalent.

- **Sterility**

For CONMED, where applicable, the Supplier shall ensure and maintain records of sterility. CONMED may specify which products require this documentation be sent with each receipt, for all others records must be maintained and provided upon request. The Supplier must maintain records of current registration with the FDA or applicable regulatory agency.



Change Control

The Supplier is responsible for controlling changes and notifying CONMED of all changes to the approved part design, manufacturing process or site.

Before submitting to CONMED a request for permanent change, the Supplier shall review the FMEA and Control Plan, as applicable, to ensure that all process-related issues have been addressed and resolved. CONMED may require the Supplier to complete an updated Supplier Readiness package.

Control of Nonconforming Material

The Supplier shall develop and maintain a documented system that controls and records the identification, segregation, disposition and correction of any nonconforming materials identified in all phases of operation from receipt, through inventory, production, inspection, stocking, and shipping.

Packaging, Labeling, Delivery, and Record Retention

Preservation, packaging, labeling and shipping methods must comply with common industry standard practices and any additional specified requirements on the CONMED engineering drawings, Purchase Order, or contracts.

- **Preservation**

To detect deterioration, the condition of the product in stock should be assessed at appropriate planned intervals. The Supplier should use an inventory management system or other documented method to optimize inventory turns over time and should assure stock rotation, such as "first-in-first-out" (FIFO).

- **Packaging**

The Supplier must adequately plan for packaging designed to prevent product contamination, deterioration or shipping damage. Suppliers should provide packaging of sufficient density, product separation and protection from any shipping damage that could likely occur. Expendable materials and packaging must meet local and national standards for safe disposal and/or recycling.

- **Labeling**

Labeling and/or bar code requirements may vary among CONMED product designs. The CONMED buyer will provide the Supplier with direction if not specified on the engineering print, purchase order or the contract.

- Delivery

The Supplier should systematically inform CONMED of any delay in delivering product and provide a new dispatch date.

- Record Retention

CONMED Corporation is a medical device manufacturer; as such we are regulated by the FDA and other International Regulatory bodies regarding record retention. This requirement extends to our supply base. Therefore, the Supplier shall document and execute a record retention policy.

SUPPLIER BUSINESS REVIEWS

Selected suppliers may undergo a review process as deemed fit by the applicable CONMED business unit. The purpose is to review supplier performance regarding quality, delivery, cost, and responsiveness. It can include topics such as strategic sourcing and new product development. Both CONMED and the supplier provide overviews of the relationship and any gaps are discussed.



CONMED CORPORATE HEADQUARTERS

525 French Road
Utica, NY 13502
Tel: 315-797-8375
Fax: 315-797-0321

www.conmed.com

