

APPLIED MEDICAL

# SUPPLIER HANDBOOK





*As a new generation medical device company, Applied Medical is equally committed to improving both the accessibility and the affordability of high-quality healthcare globally.*

*We strive to make a meaningful, positive difference in the world every day.*

# 1. Introduction

The Applied Medical Supplier Handbook provides an overview of Applied Medical and the company's expectations from their suppliers. At Applied Medical, suppliers are stakeholders. We work with our suppliers to make decisions that directly or indirectly impact our ability to provide affordable, high-quality healthcare products globally.

Given our wide range of suppliers, we understand that the expectations stated in this handbook shall apply differently, depending on the product or service offered. The handbook provides general expectations for our new and existing suppliers. Below are a few examples of what our suppliers are generally expected to do:

- Comply with applicable laws and regulations
- Behave ethically
- Maintain health and safety for all employees
- Integrate quality into all business transactions
- Protect the environment and its natural resources
- Implement systems to maintain business continuity and continuous improvements

## 1.1. PURPOSE

The purpose of the Applied Medical Supplier Handbook is to clearly communicate and document Applied Medical's expectations for how suppliers establish and maintain a business relationship with Applied Medical. The company regards this relationship as an opportunity to improve lives globally by making a meaningful, positive difference. Given that our suppliers are an extension of our business, we expect that they will see the opportunity in the same light.

## 1.2. CODE OF CONDUCT

Applied Medical is proud to have a culture strongly committed to the highest possible standards of corporate integrity and ethical behavior. The company expects its suppliers to support these standards. It anticipates that they will conduct their business not only in a lawful manner but also in compliance with the same high standards of integrity and ethics. Applied Medical also expects its suppliers to ensure and maintain safe, healthy working environments and to be committed to protecting the environment and the earth's natural resources. Suppliers are expected to comply with all applicable laws and regulations.

## 1.3. ETHICS

At Applied Medical, we create a workplace that encourages human rights and is free from discrimination and harassment. We have zero tolerance for discrimination based on physical features, cultural/socioeconomic background, nationality, sex, age, disability, health, or political or sexual preference, and for any other action that goes against the abovementioned policy and regulations, both within our operations and from our suppliers.



## 1.4. CONFIDENTIAL INFORMATION

Applied Medical's confidential or proprietary technical, operational, and business information or data ("Confidential Information") shall always be treated as confidential unless Applied Medical makes that information open to the public. To prevent any unauthorized disclosure of Applied Medical's Confidential Information, suppliers will at the very least take the highest degree of care they themselves use to protect their own information of a similar nature, but no less than a reasonable degree of care. A written consent from Applied Medical is required prior to a supplier's disclosure of Confidential Information. Confidential Information includes any confidential and/or proprietary material, information, devices, components, communication, or data in all oral, written, graphic, electromagnetic or physical forms. Examples include but are not limited to the following:

- Asset information
- Contract details
- Material specifications
- Pricing information
- Financial information
- Current or future products and services
- Technology
- Research and development
- Designs and drawings
- Inventions
- Analysis
- Techniques and processes
- Software and electronics
- Business, development and marketing plans
- Business opportunities
- Know-how
- Trade secrets
- Personal data

To ensure that Applied Medical and its team members are protected, Applied Medical may require suppliers to confirm these obligations by entering into confidentiality agreements with Applied Medical with regard to any Confidential Information.

With regard to any personal data received from Applied Medical, suppliers shall not disclose such personal data to any third parties, and the suppliers agree to retain, use, or disclose such personal data only for its intended purpose. In accordance with applicable data privacy laws, suppliers may be required to confirm these obligations contractually or by entering into a data-processing agreement with Applied Medical with regard to such personal data.



## 2. Corporate Social Responsibility

At Applied Medical, we consider how our activities and goals may contribute to the U.N. Sustainable Development Goals. We have established our Corporate Social Responsibility Committee to discuss and address global sustainability efforts and initiatives.

### 2.1. CHILD LABOR

Suppliers shall not use child labor. Any worker exposed to occupational safety and health hazards defined as hazardous work under International Labour Organization (ILO) Convention No. 182 and its Recommendation No. 190 must be at least 18 years old or of appropriate legal age. Employee files should be maintained with adequate data to verify the ages of employees.<sup>1</sup>

### 2.2. FORCED LABOR

Workers may join and leave a supplier's employment at will, provided they comply with any advance notice required by the local law.<sup>2</sup>

### 2.3. ABUSE

Workers shall not be subjected to mental abuse, physical abuse, verbal abuse, sexual abuse, or the use of language or gestures that are threatening, abusive, or otherwise inappropriate.<sup>2</sup>

### 2.4. EQUAL OPPORTUNITY

Equal opportunity shall be provided to all workers and applicants regardless of their race, religion, age, gender, nationality, disability, veteran status, or any other status protected under applicable law.<sup>2</sup>

### 2.5. WORK HOURS AND COMPENSATION

Suppliers shall establish regular work hours in compliance with the applicable local laws. Overtime shall be administered and compensated fairly and in accordance with the local law. All wages and benefits must be clearly defined and meet minimum legal and industry requirements.<sup>2</sup>

### 2.6. FREEDOM OF ASSOCIATION

Suppliers shall support the freedom of association and the rights of workers to communicate openly regarding working conditions without threat of reprisal.<sup>2</sup>

### 2.7. ENVIRONMENTAL COMPLIANCE

Suppliers shall comply with all international (if applicable), country and local laws and regulations related to the natural environment in the countries in which they operate. By identifying and managing current and future environmental sustainability initiatives, we all can reduce the impact of our activities on the natural environment and the earth's natural resources. We encourage our suppliers to report their environmental performance using ISO 14001, GRI or any other accepted reporting method.

<sup>1</sup> As mentioned in UN Convention on the Rights of the Child

<sup>2</sup> As mentioned in ILO's No. 1, 29, 87, 98, 100, 102, 105, 111, 131, 138, 155 and 182

## 3. Supplier Controls

Applied Medical thrives on delivering world-class products to those we serve – both patients and physicians. Therefore, we expect our suppliers to share in the same responsibility to meet all specified safety, compliance, quality, and reliability requirements.

### 3.1. CHANGE CONTROLS

Suppliers are expected to notify Applied Medical of any changes to their quality management systems or processes that would directly affect the company. These processes would include but are not limited to company mergers, acquisitions, changes in manufacturing processes and/or raw materials that could impact Applied Medical's products, and the acquisition of new manufacturing sites. When Applied Medical receives such notifications from suppliers, the changes will be assessed for potential impact to determine if any actions are necessary.

### 3.2. SUPPLIER QUALIFICATIONS

Applied Medical expects suppliers to manage their supply chain with proper controls based on the products or services being offered. Suppliers are expected to ensure and control the quality of all the material they supply to Applied Medical. Formal purchasing controls should be in place to manage their supply chain. These controls include but are not limited to the following:

- Supplier approval, reevaluation and monitoring
- Control plans
- Process of handling nonconforming materials or products
- Continuous improvement
- Authorized distribution

### 3.3. BUSINESS CONTINUITY

Applied Medical expects that their suppliers maintain clear disaster recovery strategies to address potential business interruptions. While these strategies may not cover all the potential scenarios, we expect our suppliers to maintain robust plans to facilitate rapid response and recovery in the event of any interruption.

### 3.4. COMPLAINTS AND ADVERSE EVENTS

Applied Medical is expected to perform timely investigations into customer complaints related to their products, in accordance with applicable regulatory requirements pertaining to the reporting of adverse events. If investigation results reveal that an external organization was implicated in the complaint, relevant information will be discussed, and records will be maintained. Suppliers, at a minimum, are expected to provide the following:

- A prompt response to Applied Medical
- A record of complaints and adverse events related to Applied Medical's products, maintained in accordance with the supplier's QMS (quality management system)
- The ability, in the event of a product recall, to establish tractability for all materials or products related to Applied Medical

### 3.5. MANUFACTURING ENVIRONMENTAL CONTROLS

Suppliers shall maintain manufacturing environmental controls, if applicable, to prevent contamination in the manufacturing area. This may involve the use of appropriate temperature, humidity, or other environmental controls, as determined by the raw material, component, or service suppliers associated with Applied Medical's products.





## 4. Nonconformance Controls

Suppliers are expected to establish and maintain procedures to control products that are nonconforming. The procedure, at a minimum, should address the identification, evaluation, investigation and handling of nonconforming products. Suppliers should have proper controls in place, such as incoming, in-process and final inspections to detect nonconformance prior to shipment to Applied Medical. All results from the inspections should be properly documented.

### 4.1. CORRECTIVE AND PREVENTIVE ACTION (CAPA)

Suppliers are expected to establish and maintain a CAPA system if such a system is applicable to their quality management system. The CAPA system helps in identifying the root cause of the nonconformance. When a CAPA is initiated, the following basic elements of the CAPA system are implemented and documented:

- Identifying and containing the nonconformity
- Investigating the root cause and evaluating risk
- Identifying action(s) needed and implementing changes
- Performing an effectiveness check

### 4.2. SUPPLIER CORRECTIVE ACTION REQUEST (SCAR)

When a nonconforming material or product is received from a supplier, Applied Medical may initiate a SCAR if the relevant triggers have been met. Suppliers are expected to review the SCAR, investigate the issue, and respond to Applied Medical, describing any action taken to prevent the nonconformance from happening again. Applied Medical will review the response from the supplier and, if appropriate, perform an effectiveness check based on the action items described by the supplier.

## 5. Supplier Audit

Applied Medical may choose to audit the supplier's or sub-tier supplier's manufacturing and quality management systems and, if applicable, environmental management system, either remotely or on-site. To ensure compliance with quality requirements, Applied Medical expects to be given access to observe and inspect the suppliers' manufacturing environment:

- The manufacturing facility
- The quality management system
- Processes as they relate to Applied Medical products

Upon completion of these audits, Applied Medical will communicate the findings. Suppliers are expected to provide a timely written response to all Applied Medical's audit findings that are classified as nonconforming.

Notified bodies, which ensure the safety of the medical devices sold, conduct unannounced audits of medical device manufacturers. An unannounced audit by a notified body at Applied Medical's facility may result in an audit at the facilities of critical contract manufacturers or critical service suppliers involved with producing Applied Medical's products.

## 6. Continuous Improvements

Applied Medical thrives on being a reliable manufacturer that consistently and continuously delivers quality products to its customers. To achieve this, we need support from a strong supply base. Therefore, we expect our suppliers to follow a continuous improvement program. At Applied Medical, we constantly find ways to reduce waste, reduce our environmental impact, optimize manufacturing processes, and optimize our supply chain. We require our suppliers to either follow an effective program of their own or, if they prefer, align themselves with Applied Medical's continuous improvement methodology.

We at Applied Medical appreciate the time you've taken to review our expectations. As stated in this handbook, the expectations can be adjusted according to the product or service you provide. If you have any questions regarding our supplier handbook, you can contact us at [SupplierControls@appliedmedical.com](mailto:SupplierControls@appliedmedical.com).



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