Customed Supplier Quality Requirements

1. Supplier Requirements Overview

Suppliers are responsible for ensuring that Products or services meet established Customed specifications and Quality Requirements. Audits, approvals or verification by Customed of the Supplier's facility, quality system, process controls, acceptance activities, etc., does not absolve the Supplier of the responsibility to provide acceptable Product, nor will it preclude the subsequent rejection of unacceptable Product.

This Manual contains requirements for all Supplier types: raw and manufacturing material, component, OEM and Contract Manufacturers of medical finished devices, and Service Suppliers.

In reading the requirements in this Manual, it is important to note the following terms:
• Should, may, expect – Action is strongly recommended
• Must, will, shall – Action is required

1.1. Quality Agreements

In addition to the requirements contained in this Manual, Customed will determine if a Quality Agreement is needed between Customed and the Supplier. Once the need is determined, it is our expectation that the Supplier will work with Customed to put this agreement in place.

1.2. Environmental Compliance

As a Customed supplier we expect that your Products, components or substances supplied to Customed will meet the requirements of country, federal, state and local environmental regulations.

1.3. Import Compliance

As business becomes increasingly globalized, additional documentation and processes are required. If a Supplier is shipping Product to Customed from outside the United States border, there are several key things to know.

Country of Origin is defined by the country of manufacture, production or growth of any article of foreign origin entering the U.S. Further worked or material added to an article in another country must affect a substantial transformation in order to render such a country as the country of origin.

Customed requires that unless excepted by law, every article of foreign origin, or its container imported into the U.S. shall be marked in a conspicuous place as legibly, indelibly and permanently as the nature of the article or container will permit in such manner as to indicate the country of origin to an ultimate purchaser in the U.S., the English name of the country of origin of the article.

A commercial invoice signed by the seller, shipper or associated agent is required for Customs entry and is acceptable if prepared in accordance with 19 CFR 141.86 of the customs regulations. Any inaccurate or misleading statement of fact in the commercial document may result in delays in release, detention of goods, increased review by import specialists or penalties against the importer.

Wood Packaging Material is closely regulated as it pertains to importation of goods into the U.S. The Animal and Plant Health Inspection Service USDA, have amended the regulations for the importation of unmanufactured wood articles to adopt an international standard entitled "Guidelines for Regulating Wood Packaging Material in International Trade" that was approved by the Interim Commission on Phytosanitary Measures of the International Plant Protection Convention on March 15, 2002. The standard calls for wood packaging material to be either heat treated or fumigated with methyl bromide, in accordance with the Guidelines, and marked with an approved international mark certifying treatment. This change will affect all persons using wood packaging material in connection with importing goods into the United States. Effective Date: September 16, 2005. Please refer to the following link for more information:

http://www.cbp.gov/linkhandler/cgov/import/commerical_enforcement/wpm/importation_wood.ctt/importation_wood.pdf

1.4. Business Continuity

As a responsible medical device manufacturer, we expect our Suppliers to complete a formal Business Continuity/Disaster Recovery Plan to ensure no interruption in supply to our patients is encountered. While it is apparent that contingency plans cannot be developed for all potential scenarios, we expect our Suppliers to have/maintain robust plans to facilitate rapid response and recovery in the event of disruptions.

Upon request, the Supplier shall provide risk management and business continuity plans to Customed.

Customed expects its Suppliers to develop, deploy, maintain, and adhere to these business continuity planning requirements at all times.

1.5. Non-Disclosure Agreements

As a Supplier to Customed you may be asked to sign a non-disclosure agreement depending on the level of technology or information disclosed during the course of business. Information provided to Suppliers involving various trade secrets, designs, materials and other proprietary information of a secret and confidential nature may include, but are not limited to records, data, schedules, forecasts, formula, processes, procedures, specifications, developments, designs, inventions, models, techniques, improvements or discoveries, patentable and otherwise.

It is Customed's policy that Suppliers shall not use, transmit or disclose confidential information to any third party except in accordance with the terms of the non-disclosure or any other written agreement. Supplier shall not make any public announcement about or

advertise the existence of this agreement, divulge its terms and conditions or any relationship with Customed other than with prior written agreement of the other party. Suppliers shall agree not to display or use the Customed logo, trade secrets, trademark, or product(s) in any manner without our prior written permission.

Customed values our relationships with our Suppliers and therefore would like to protect it through the use of this formal agreement.

1.6. Change Management:

The continuous improvement philosophy encourages process improvements. However, the supplier shall notify Customed prior to any modification including but not limited to component changes, material or chemical composition changes, process changes, design changes or deviations being implemented. The supplier must complete all verifications and tests to ensure that a new process continues to yield components that meet specification prior to full implementation in production and subsequent production shipments.

The supplier must notify Customed prior to implementing any change.

1.7. Sub-Tier Supplier Control:

The Supplier must maintain qualifications for subcontractors and the products purchased through them. It is the Suppliers' responsibility to ensure and control the quality of all components and raw materials that are purchased to manufacture components and parts for Customed.

Suppliers will manage sub-tier suppliers with controls commensurate with those Customed applies to direct suppliers.

1.8. Cost of Poor Quality (COPQ)

In the event that any Product has been rejected and Customed has notified Supplier, Supplier shall replace such Product free of charge and Supplier shall cover expenses (including freight and customs clearance, if any) incurred by Customed in connection with (a) shipment of replacement Product to the same location and (b) shipment of the Nonconforming Product back to Supplier (if so requested by Supplier). In the event of a rejection of defective Product, Supplier shall ship replacement Product as soon as practical, but in any event within thirty (30) days of its receipt of a proper rejection notice from Customed. Failure to meet such deadline shall result in a 5% decrease in price associated with the replacement Products. Supplier shall also reimburse Customed up to an amount equal to scrap and/or rework costs as a result of using the Nonconforming Product in production.

2. Quality Management System

2.1. Expected Requirements

The Supplier expectations are dependent on the Supplier type and category, as outlined in the table below:

Supplier Type	Supplier Category	Minimum Requirement	Preferred
Raw Material, Component, and Component Services	New or Existing	Working towards ISO 9001:2008 certification	ISO 13485:2003 certified
OEM and Contract Manufacturing of Finished Devices	New or Existing	ISO 13485:2003 certified and FDA Registered	N/A

For existing Suppliers that are not certified to the specified ISO standard referenced above, it is preferred that those Suppliers have a plan in place to become certified and can demonstrate progress toward that plan.

Suppliers that are ISO certified, must notify Customed Supply Chain in writing within five (5) business days if their Quality System certification is suspended, placed on probation, expired, receives any major non-conforming compliance from ISO notified bodies, or if the Supplier has been placed on any special status with their customers or registrars due to quality or delivery issues. The Supplier must also provide immediate notification to Customed if it receives a 483 or warning letter from the FDA. New Quality System certification shall be provided where there are mergers, acquisitions, or affiliations associated with Suppliers. Customed and its customers reserve the right to verify conformance of Supplier's Quality System to ISO standard.

Upon request, Suppliers shall forward evidence of their Quality System certification to Customed.

2.2. General Requirements for Suppliers

Suppliers are required to establish, document, and implement an effective Quality Management System. The Supplier's management will ensure that the Quality Requirements, including without limitation, in this Manual are thoroughly distributed, understood, and maintained.

2.3. Documentation Required

2.3.1. General

The Quality Management System documentation must include:

- Documented statements of a quality policy and quality objectives
- Documented procedures as required by the Quality Management System

• Documents needed by the organization to ensure the effective planning, operation and control of its processes
• Records required by the Quality Management System

2.3.2. Control of Documents

Supplier must establish, maintain, and document procedures to control all Quality Management System documentation and all data generated under the Quality Management System. The Supplier must have current revisions of documents available at all appropriate locations.

Supplier must have a documented procedure for the control and distribution of drawings and/or standards.

Obsolete drawings must be destroyed or appropriately identified as such for limited distribution.

2.3.3. Control of Records

Records must be stored in an environment that will prevent deterioration, damage, or loss, and must be readily accessible to Customed upon request.

Supplier will make available any and all quality Records, within two (2) working days, upon request by Customed or any regulatory body such as the FDA.

Electronic record approvals and storage should comply with 21 CFR Part 11 requirements.
Record Retention (Applicable to OEM and Contract Manufacturing of Finished Devices)
• All quality Records shall be retained for a period of time equivalent to the design and expected life of the device, but in no case less than two (2) years from the date of release for commercial distribution by the manufacturer.
Record Retention (Applicable to Raw Material, Component, and Component Services)
• All quality Records must be kept for at least five (5) years, or as otherwise required by a Quality Agreement, except internal audit and Supplier audit records, which shall be retained for at least two (2) years.

2.4. Complaints and MDR Handling

The parties will cooperate in dealing with customer and third party complaints concerning the Product(s) and shall take action to promptly resolve such complaints as may be reasonably requested by the parties.

Supplier shall:
• Give notice to Customed by email or by telephone within 24 hours of becoming aware of a Product complaint, with written follow-up within three (3) days.
• Maintain a written Record of all customer and third-party complaints that relate to the Product(s), whether received orally or in writing;
• Establish a tracking system for all Product(s) so as to permit successful tracking in the event of a Recall.

• Maintain complaint Records and files in accordance with the Supplier's Quality System requirements.

Customed shall have the sole authority to correspond with all applicable regulatory authorities with respect to complaints about the Product(s).

If Supplier becomes aware of a potentially MDR reportable event, notice of such event shall be given to Customed within two (2) business days. If the event may have caused or contributed to a death or serious injury, Supplier shall notify Customed within twenty four (24) hours of becoming aware of the issue.

2.5. Recalls

If the Supplier determines that a Recall or other action involving a Product(s) should be considered, it will immediately notify Customed. Customed will have the sole authority to determine whether any action such as a Recall or other action should be undertaken. Supplier will cooperate with Customed to implement the Recall once the determination is made.

3. Supplier's Obligations for Timely and Proper Notification of Change

3.1. Changes by Customed

The Specifications may be revised by Customed. Such revisions may require additional qualification.
Customed shall notify Supplier of all relevant Specification revisions. Supplier shall implement all revisions by dates specified by Customed.

3.2. Changes by Supplier

Component or process changes, design changes or deviations considered by Supplier must be submitted to Customed in writing for review and approval prior to making any changes.
When Supplier submits changes for Customed's approval, the information submitted must include a complete description of the change and, working jointly with Customed, Supplier must determine the effect the change will have on all characteristics of the Product.
Upon request, the Supplier shall submit samples of the proposed Product for evaluation and approval by Customed. Supplier shall not implement any such change without Customed's prior written consent.
Supplier shall ensure that entities that supply Components follow this same procedure.

3.3. Change/Approval

Customed personnel shall review and approve changes that may affect the Product(s), including, without limitation:
All process changes including changes related to:
• Field action
• Product performance issue
• Process validation
• Process deviation
• Process Failure Modes & Effects Analysis (PFMEA)

• Product final acceptance test issue
• Supplier manufacturing site transfers
• Sub-Tier Supplier changes

Material:
• Changes to materials and/or Components
• Change in a supplier of a material or Component

Change in Component or Product requiring:
• Updated component specification
• Updated product specification
• New or alternate Sub-Tier Supplier

CAPA:
• CAPA initiation involving Customed products

Change in Supplier:
• Name
• Address

Change in Product design:
• Product
• Labeling
• Packaging

Change to Product part number

Change to Manufacturing, test, or inspection equipment:
• New equipment
• Equipment qualification or validation
• Change from manual to automated process

Facility Changes:
• Move of manufacturing equipment within the same manufacturing facility.
• Facility to facility transfer of manufacturing processes or technology.
• Altering environment specs or conditions in areas used for manufacturing, storage, or test (i.e. microbial/endotoxin/particulate monitor).

In-process and final acceptance test changes related to:
• Test specification
• Test application validation
• Outgoing inspection plan
• Test acceptance requirements
• Products reviewed by Supplier MRB for "Use As Is" disposition

3.4. Design and Development

Supplier may collaborate with Customed to ensure a thorough understanding and identification of critical process steps, transfer function relationships, acceptable measurement capability, and process capability of process inputs/outputs related to their impact on the critical design features. Supplier may collaborate with Customed to design an appropriate control plan to help ensure the long-term stability and capability of the manufacturing processes with the goal of achieving a high process capability.

3.4.1. Design and Development Planning

Supplier may establish and maintain plans that:
• Describe or reference the Design and Development activities for the Product

• Identify and describe the interfaces with the groups or activities that provide input to the design/development process for the Product
• Define responsibility for implementation in substantial compliance with Quality Management System Requirements.

3.4.2. Design Inputs

Customed, through the use of Design for Reliability and Manufacturing methodology, may collaborate with the Supplier to ensure that the design requirements for the Product are appropriate for and address the intended use of the Product. This includes the needs of the user and patient, in compliance with the Quality Management System Requirements. In addition, Customed may identify all critical features and/or requirements of the Product that require specific capability and control within the Supplier's manufacturing process. These will be reported to Customed using electronic data collection system or other agreed upon format. The design requirements should be documented and approved by the appropriate Supplier personnel.

3.4.3. Design Outputs

Supplier may establish and maintain procedures for defining and documenting Design Outputs in a manner that allows adequate evaluation of the Product's conformance to Design Input requirements, in substantial compliance with Quality Management System Requirements. The procedures may reference acceptance criteria and may ensure that essential outputs are identified. Supplier may document Design Output.

3.4.4. Design Review

Supplier may establish and maintain procedures to ensure that formal documented reviews of the design for the Product are planned and conducted at appropriate stages in design development, in substantial compliance with Quality Management System Requirements.

3.4.5. Design Verification

Supplier may establish and maintain procedures for verifying the design of the Product, in substantial compliance with Quality Management System Requirements. Design verification may confirm that the Design Output for the Product meets the Design Input requirements and any other Customed requirements.

3.4.6. Design Validation

Supplier may establish and maintain procedures for validating the design of the Product. Design validation may be performed under defined operating conditions on initial production units, lots or batches, or their equivalents.
Design validation may ensure that the Product conforms to defined user needs and intended uses, and may include testing of the Product under actual or simulated use conditions.

3.4.7. Design Transfer

Supplier may establish and maintain procedures to ensure that the design of the Product is correctly translated into production specifications, in substantial compliance with Quality Management System Requirements.

3.4.8. Design Changes

Supplier may establish and maintain procedures for the identification, documentation, validation (or where appropriate, verification), review and approval of design changes for the Product before implementation, in substantial compliance with Quality Management System Requirements. Supplier may suggest and request design changes to Customed, but Supplier shall not implement any design change before receiving updated specifications and appropriate change authorization from Customed.

3.4.9. Control of Design and Development Changes

Supplier may have procedures for the identification, documentation, and validation of design changes. Supplier shall notify Customed, prior to implementation of design changes that may affect the safety, effectiveness, use or performance of the Component or Product. Supplier shall follow all appropriate change control procedures. Any changes to product design require appropriate change authorization from Customed.

3.4.10. Design History File (Applicable to OEM Suppliers Only)

OEM Suppliers are responsible for maintaining a Design History File (DHF) for the Product. This will contain or reference the records necessary to demonstrate that the design was developed in accordance with the design plan, per the applicable Quality System Requirements.

OEM Supplier shall retain records of the Product DHF for the agreed upon time, as stated in the Quality Management Agreement. Supplier shall grant Customed access to the DHF within twenty-four (24) hours of request.

OEM Suppliers shall document results of the design reviews, design verification and the design validation.

4. Purchasing

Supplier shall establish and maintain controls on the purchase of components used in the manufacture of Product to ensure conformance to specified requirements, including visual inspection of packaging, labeling, or shipping containers, and dimensional inspection or analytical testing.

Supplier shall maintain documentation that clearly describes the quality requirements for components, and shall require component sources to notify Supplier of any proposed changes in the manufacturing of the components prior to making any change.

In the event that Supplier subcontracts a portion of the manufacture and/or inspection of components to sub-tier suppliers, the requirements defined in this document shall be passed on to those Suppliers through purchase order requirements. Supplier shall remain responsible for all acts or omissions of the sub-tier supplier with whom it contracts.

4.1. Production and Service Provision

Suppliers must incorporate and document process controls as needed to ensure stable conditions for the manufacturing process. Process controls documents include, but are not limited to, process sheets, inspection and test instructions, test procedures, standard operating procedures, preventive maintenance instructions and process control plans.

On an ongoing basis, the Supplier shall monitor production and complete inspection of each lot/batch of shipment per the outgoing inspection plan to ensure conformance. The Supplier

will include a Certificate of Conformance (COC) for each lot/batch based on conformance to both plans.

5. Identification and Traceability

5.1. Identification

Supplier will establish procedures that identify product during all stages of receipt, production, and distribution.
Supplier shall have systems in place that provide a means of identifying the status of Product not yet transferred to Customed or a contract manufacturer.
At a minimum, identification and segregation is required for:
a) Receiving Inspection
b) Production work in progress
c) Nonconforming Product
d) Reject Product
e) On-hold (quarantined) Product
f) Conforming Product

5.2. Traceability

Supplier shall be responsible for setting up and maintaining controlled documentation of product traceability during all stages of receipt, production, and distribution. Traceability and quality records will be maintained throughout the life of the Product, as determined by Customed. Traceability requirements include, but are not limited to, the following:
a) Minimum Traceability – All Products and components are traced by lot/batch.
b) Process Information – Traced to the sub-assembly. At a minimum, this includes the operator, date performed, shift, manufacturing instructions used, use of validated equipment and identification of equipment used, Bill of Material (BOM)/design revision and configuration, resolution of any discrepancies, and record of any rework performed.
c) Raw Materials – Traced to original material manufacturing lot/batch at a minimum.
d) These records will be made available to Customed upon request.

5.3. Handling, Storage, Distribution, and Installation

Supplier shall establish and maintain procedures for the handling, storage, distribution, and installation of the Product(s) in substantial compliance with the following:
a) Handling: Supplier shall have systems in place to ensure that mix-ups, damage, deterioration, contamination, or other adverse effects do not occur during handling of the Product(s).
b) Storage: Supplier shall control storage areas to prevent mix-ups, damage, deterioration, contamination, or other adverse effects pending distribution of the Product(s).
c) Distribution: Supplier shall have systems in place to control distribution of Product(s) so that only Product(s) approved for release are distributed. Supplier shall ensure that no obsolete, rejected, expired, or deteriorated Products are distributed, unless they are distributed to Customed at its request.
d) Installation: When a Product requires installation, Supplier shall have adequate installation, inspection, and testing instructions and procedures, where appropriate, which meet Customed requirements. Instructions and procedures will include directions for ensuring proper installation. Supplier shall distribute the instructions and procedures with the

Product or otherwise make them available to the person installing the Product. The person installing the Product will perform installation, inspection, and testing in accordance with the instructions and procedures.

5.4. Control of Monitoring and Measuring Devices

Supplier must establish and maintain documented procedures for the calibration, control, and maintenance of measuring, inspection, and test equipment used to ensure that products and processes conform to applicable requirements. A Supplier must calibrate these devices at consistent periodic intervals against applicable standards traceable to NIST (National Institute of Standards and Technology), and safeguard the devices against adjustments that would invalidate the calibration. If a Supplier finds that a gauge is not calibrated correctly and it has been used to verify parts for Customed, the Supplier must notify Customed.

6. Measurement, Analysis, and Improvement

6.1. General

Measurement, analysis, and improvement are the processes of planning, defining, and using performance metrics for products delivered to Customed. These performance metrics determine the current level of performance, drive continuous improvement activities, and monitor performance levels. Statistical tools must be applied to measure the performance metrics on processes and products, but also to measure supply chain performance. Supplier must define, plan, and implement measurements where processes affect the quality of products or services that Customed receives.

6.2. Production and Process Control

Supplier will have systems in place to define and maintain the manufacturing process and associated controls so that all Product conforms to their specifications, including, but not limited to:

a) Approved and documented production processes, instructions, and methods that define and control the manner of production.

b) Monitoring and control of process parameters and component and device characteristics during production.

c) Compliance with specified reference standards or codes.

d) Approval of processes and process equipment.

Supplier will monitor and control the manufacturing process using industry standard tools, such as: in-process inspection; control plans; validation; and Statistical Process Control.

At a minimum, Special Processes used for the manufacture of any finished device shall be validated and require a control plan. This includes any process that may be performed by sub-tier suppliers.

Supplier will identify and document key manufacturing process steps that affect product performance.

In the event that any of the manufacturing process steps are out-of-control or manufacturing yields decline considerably, Supplier will take appropriate corrective and preventive actions to rectify the situation, while documenting actions taken.

6.3. Audits

Customed may choose to audit the Supplier or sub-tier Supplier's manufacturing and Quality Systems. To ensure compliance to Quality Requirements, it is expected that during these audits, Customed shall have reasonable access to observe and inspect Supplier's:

• Facility, manufacturing, and quality control processes • Manufacturing and quality control records

• Quality Systems and all analytical and manufacturing documentation related to Product

Supplier will conduct internal audits to ensure compliance with its Quality System and this Quality Manual. Upon request, the Supplier will provide audit results and conclusions to Customed.

6.4. Monitoring and Measurement

6.4.1. Incoming Acceptance

Supplier shall have procedures for acceptance of incoming product, including inspection, testing, and verification as conforming to Customed specifications. Supplier will document acceptance or rejection of incoming product.

Certified Components that are received shall include a certificate of compliance to Supplier's specification.

6.4.2. In-Process Acceptance

Supplier shall have in-process acceptance procedures to ensure that in-process Product is controlled until the required inspection and tests or other verification activities have been completed, or necessary approvals are received.

6.4.3. Final Acceptance

Supplier shall have procedures for finished Product acceptance to ensure that each production unit, lot, or batch of finished Product meets acceptance criteria. Finished Product shall be adequately controlled until released.

6.5. Control of Nonconforming Product

Supplier will establish and maintain procedures to control Product that does not conform to specifications.

The procedures shall address the identification, documentation, evaluation, segregation, and disposition of Nonconforming Product, including the need for an investigation, which shall be documented.

6.5.1. Material Corrective Action Request/Supplier Corrective Action Request (SCAR)

Where a Product is identified by Customed as Nonconforming Product, Supplier shall cooperate with Customed in working toward closure of the Customed Corrective Action Request associated with the Product(s).

6.5.2. Product Performance

Nonconforming Product may be returned to Supplier for investigation and analysis by Customed, a third party, or through Supplier's own vigilance. In the latter two, Supplier

shall promptly notify Customed when Nonconforming Product is returned. Supplier and Customed shall agree on the necessary analysis to be performed by Supplier.
Supplier shall follow their own failure analysis protocol in performing root cause analysis, if available.

6.5.3. Escapes

Supplier shall have control systems in place to prevent Nonconforming Product from being integrated with conforming Product. In the event these systems fail, Supplier shall immediately notify Customed by telephone and email of escapes of Nonconforming Product, to allow Customed to investigate and take containment action.
Supplier shall fully cooperate in any investigation of containment action.

6.5.4. Disposition of Nonconforming Product

Supplier shall have procedures covering disposition of Nonconforming Product, including review and documentation of decisions. Customed and Supplier shall jointly determine the procedures for rework, retest, and re-evaluation of Nonconforming Product to ensure Product meets specifications.

6.6. Corrective and Preventive Action (CAPA) System

Supplier will establish and maintain procedures for implementing a CAPA system in substantial compliance with the industry standards and Quality Management System requirements. The CAPA system shall include, at a minimum, the following requirements:
• Analysis of quality data (e.g., manufacturing processes, operations, quality audit records and reports, complaints, returned Product) to identify root causes of Nonconforming Product or other quality problems
• Investigation of the causes of nonconformities
• Identification of the actions needed to correct the nonconformance and to prevent reoccurrence
• Verification or validation of the corrective and preventive action
• Documentation of changes implemented to methods and procedures to correct and prevent quality problems
• Implementation of and recording changes to methods and procedures needed to correct and prevent quality problems.
• Documentation that information regarding quality problems or Nonconforming Product is disseminated to appropriate quality personnel
• Submission to management of relevant information regarding quality problems, plus corrective and preventive action
• Documentation of activities under the CAPA system
• Effectiveness verification of corrective and preventive action

Supplier shall resolve and document any product quality, Quality System, or performance issues within the CAPA framework. Supplier will:
• Review nonconformities, including customer complaints
• Perform failure/root cause analysis
• Evaluate the need for action to ensure that nonconformities do not recur
• Determine and implement action needed
• Record the results of any investigation and action taken

• Review the corrective action taken to ensure its effectiveness

Supplier shall provide action plans including responsible personnel and targeted completion dates for all corrective action requests within thirty (30) days of notification, unless otherwise noted in a Customed contract or agreement.

Action plans shall be verified and/or validated to ensure effectiveness without an adverse affect on Product or process.

To eliminate the possibility of human error, mistake-proofing will be incorporated when and where possible.

Supplier shall meet commitment dates to ensure timely resolution of all identified issues.

Supplier shall notify Customed in writing within two (2) working days after learning of any actual or potential problems relating to the performance of any Product manufactured for Customed that does not meet specification.