Exhibit 10.15  
  
MANUFACTURING AND SUPPLY AGREEMENT  
  
This Manufacturing and Supply Agreement (this “Agreement”) is effective as of December 15, 2015 (the “Effective Date”) and is made by and between Clinical Micro Sensors, Inc. d.b.a. GenMark Diagnostics, Inc. (“GenMark”), a Delaware corporation with its principal place of business at 0000 Xx Xxxxx Xxxxx, Xxxxxxxx, Xxxxxxxxxx 00000, and Plexus Corp. (“Plexus”), a Wisconsin corporation with its principal place of business at Xxx Xxxxxx Xxx, Xxxxxx, Xxxxxxxxx 00000.  
  
RECITALS  
  
WHEREAS, GenMark is engaged in the business of designing, developing and marketing molecular diagnostic instruments, consumables assays, and other products;  
  
WHEREAS, Plexus has expertise in the design, development and manufacture of complex diagnostic instruments; and  
  
WHEREAS, GenMark has requested that Plexus manufacture and supply the Products (as hereinafter defined) on the terms and the conditions set forth herein.  
  
AGREEMENT  
  
NOW, THEREFORE, in consideration of the mutual promises, covenants and agreements herein set forth, and for other good and valuable consideration the receipt and sufficiency of which is hereby acknowledged, the parties hereto agree as follows:  
  
ARTICLE I  
DEFINITIONS  
 Capitalized terms used in this Agreement and not otherwise defined herein shall have the meaning set forth below.  
  
  
1.1 “Affiliate” means, with respect to a party, any Person that directly or indirectly through one or more intermediaries, controls, is controlled by or is under common control with a party. For this purpose, control of a Person that is a corporation or other business entity shall mean direct or indirect beneficial ownership of fifty percent (50%) or more of the voting interest in, or a fifty percent (50%) or greater interest in the equity of, such corporation or other business entity.  
  
1.2 “Applicable Standards” means, collectively, (a) the applicable requirements as described in the Manufacturing Documents, (b) all applicable laws and regulations, including, but not limited to, the Federal Food, Drug and Cosmetics Act, as amended, cGMP, and the European Medical Device Directive 93/42/EEC, (c) all applicable environmental, health, and safety laws; and (d) ISO 13485 and 9001.  
  
1.3 “Base” means a computer and display unit to which between one (1) and four (4) Towers may be attached to operate GenMark’s integrated, fully-automated molecular diagnostics ePlex™ instrument system, as more fully described in the Specifications.  
  
1.4 “Base System” means an integrated, fully-automated molecular diagnostics ePlex™ instrument system comprising one (1) Base, two (2) Towers, and twelve (12) Bays, as more fully described in the Specifications.  
  
1.5 “Bay” means each of six (6) removable, autonomous processing units which can accept a consumable cartridge that contains the reagents and instructions for a diagnostic test, as more fully described in the Specifications.  
  
1.6 “Xxxx of Materials” means the list of the raw materials, sub-assemblies, intermediate assemblies, sub-components, parts and the quantities of each needed to manufacture the Products, in each case as set forth in the Specifications.  
  
1.7 “cGMP” means current good manufacturing practices, including, without limitation, the FDA’s Quality System Regulations, pursuant to Title 21 of the United States Code of Federal Regulations, Part 820, as applicable to the manufacture of a medical device.  
  
1.8 “Change Control” means a set of secure processes and procedures that are used to track and document versions of Product documentation that satisfies all requirements of the Applicable Standards for the manufacture of Products by Plexus  
  
  
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under this Agreement, which processes and procedures shall include a requirement for prior written approval by GenMark of all changes or improvements to the Product.  
  
1.9 “FCA” means “Free Carrier (named place of destination)”, as that expression is defined in Incoterms 2010, ICC Publishing S.A.  
  
1.10 “Facility” means Plexus’ manufacturing facility located at 0000 Xxxxxxxxx Xx., Xxxxxxx Xxxxx, Xxxxxxxx 00000, which shall be used to manufacture and produce Products for GenMark hereunder, or such other facility at which Products are manufactured as the parties may mutually agree in writing from time to time during the term of this Agreement.  
  
1.11 Reserved.  
  
1.12 “FDA” means the United States Food and Drug Administration or any successor agency thereof.  
  
1.13 Reserved.  
  
1.14 “GenMark Equipment” means the equipment, test fixtures, molds, devices, tools and other apparatuses located at the Facility and used to manufacture and/or test Products hereunder which are owned by GenMark, as further described in Section 4.1 hereto.  
  
1.15 “GenMark Intellectual Property Rights” means all Intellectual Property Rights owned or controlled by GenMark as of the Effective Date or during the term of this Agreement.  
  
1.16 “Governmental Authority” means any country, including any political subdivision, court, instrumentality, or agency thereof, and any other federal, state, or public authority, domestic or foreign, exercising governmental powers and having jurisdiction, and all statutes, laws, ordinances, regulations, orders, decrees, permits, writs, processes and rules issued thereby which may be applicable to the parties’ performance under this Agreement.  
  
1.17 An “Insolvency Event shall be deemed to have occurred with respect to a party if such party: (a) is unable to pay its debts as such debts become due; (b) makes a general assignment for the benefit of creditors; (c) has a petition in bankruptcy or a suit seeking reorganization, liquidation, dissolution, or similar relief filed against it; (d) files or permits the filing of any petition or answer seeking to adjudicate itself bankrupt or insolvent, or seeking for itself any liquidation, winding up, reorganization, arrangement, adjustment, protection, relief, or composition of such party or its debts under any law relating to bankruptcy, insolvency, or reorganization or relief of debtors, or seeking or consenting to the appointment of a trustee, custodian, receiver, liquidator or other similar official for itself or for any substantial part of its property; or (e) takes any corporate action to authorize any of the foregoing actions.  
  
1.18 “Intellectual Property Rights” means, collectively, all of the following intangible legal rights, whether or not filed, perfected, registered or recorded and whether now or hereafter existing, filed, issued or acquired: (a) inventions, patents, patent disclosures, patent rights, including any and all continuations, continuations-in-part, divisionals, reissues, reexaminations, utility models, industrial designs and design patents or any extensions thereof; (b) rights associated with works of authorship, including, without limitation, copyrights, copyright applications and copyright registrations; (c) rights in trademarks, trademark registrations and applications therefor, trade names, service marks, service names, logos, or trade dress; (d) rights relating to the protection of formulae, trade secrets, know-how and Confidential Information; and (e) all other intellectual or proprietary rights.  
  
1.19 “Manufacturing Documents” means, collectively, the Specifications, the Xxxx of Materials, the Testing Criteria, the Quality Agreement, and such other manufacturing and quality assurance documentation setting forth the requirements in respect of the manufacture, storage, shipping, labelling, testing, supply, release and acceptance of Products hereunder.  
  
1.20 “Manufacturing Instructions" means the manufacturing instructions prepared by the parties on behalf of GenMark, for the manufacture of the Products, as the same may be amended from time to time by written agreement of the parties during the term of this Agreement.  
  
1.21 “Material” means, collectively, all raw materials, items on the Xxxx of Materials, packaging materials, labeling materials and other materials required to manufacture and supply the Products to GenMark in accordance with the Manufacturing Documents.  
  
1.22 “Person” means any natural person, corporation, firm, business trust, joint venture, association, organization, company, limited liability company, partnership or other business entity, or any Governmental Authority.  
  
  
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1.23 “Products” means the beta units designated by GenMark in writing as saleable for commercial use and the production versions (including future versions thereof) of GenMark’s integrated, fully-automated molecular diagnostics ePlex™ instrument system, comprising Bases, Bays, and Towers, to be manufactured and supplied by Plexus in accordance with this Agreement and the Manufacturing Documents.  
  
1.24 “Program Material” shall mean the Technical Design History File (DHF) and Device Master Record (DMR) for the Products prepared and maintained in accordance with the Applicable Standards, the Manufacturing Instructions, and all other quality, compliance, manufacturing, engineering and technical documentation, instructions and information, product declarations, certifications, and reports (including design verification and test reports) related to the manufacture of the Products hereunder or that are sufficient or reasonably required to allow GenMark to manufacture the Products.   
  
1.25 “Quality Agreement” means that certain Quality Assurance Agreement attached hereto as Exhibit A.  
  
1.26 Reserved.  
  
1.27 “Safety Stock” has the meaning set forth in Section 2.6 hereof.  
  
1.28 “Spare Parts” means the spare parts for the Products to be identified and developed by the parties pursuant to Section 2.2 below, which shall be manufactured and/or supplied by Plexus pursuant to the terms of this Agreement.  
  
1.29 “Supply Failure” means a failure by Plexus to supply Products or Spare Parts ordered pursuant to this Agreement on the Delivery Date or up to three (3) days prior to the Delivery Date for any reason other than Force Majeure (as defined in Section 11.6).  
  
1.30 “Specifications” means GenMark’s written specifications for the Products, manufacturing requirements, instructions, shipping,storage and labelling requirements, and quality control specifications and documentation, which are identified on Exhibit B or otherwise communicated by GenMark and accepted by Plexus in writing.  
  
1.31 “Testing Criteria” means the quality control, inspection, release, and testing procedures to be performed by Plexus and related criteria to be achieved in testing for final Product release, the current version of which are set forth in the Specifications, as the same may be amended from time to time by mutual written agreement of the parties.  
  
1.32 “Tower” means a tower which contains six (6) Bays and attaches to a Base, as more fully described in the Specifications.  
  
ARTICLE II  
PURCHASE OF PRODUCTS AND TERMS OF SALE  
  
2.1 General. During the term of this Agreement, Plexus shall manufacture and sell to GenMark, and deliver to GenMark or its designees, the Products ordered by GenMark pursuant to the terms of this Agreement. Plexus shall not sell, transfer or deliver any Products to any party other than GenMark or its designee, except with GenMark’s prior written consent. During the term of this Agreement and thereafter, GenMark shall have the exclusive right throughout the world to market, sell, place, lease or otherwise transfer Products to third parties and provide or have provided related repair and service support to its customers, including the provision of Spare Parts.  
  
2.2 Spare Parts. Plexus shall supply Spare Parts for the Products as required by GenMark during the term of this Agreement. Not later than three (3) months following initial delivery of commercial Products, the parties will agree on the type and quantity of Spare Parts that are advisable to maintain in stock, and on a reasonable Spare Parts use and repair implementation plan, in each case to establish and maintain technical support of the Products for GenMark’s customers, which the parties agree shall include certain field service and repair activities that may be performed by GenMark or its authorized third party representatives (“GenMark Field Service”). An initial Spare Parts list established by the parties and related prices therefor, as well as the GenMark Field Service mutually agreed by the parties, in each case as of the Effective Date, are set forth on Exhibit C hereto. The parties expect to further augment and/or modify the list of Spare Parts set forth on Exhibit C hereto and, in connection therewith, the parties shall negotiate in good faith to conclusion GenMark’s related price for any additional Spare Parts not reflected on Exhibit C hereto as of the Effective Date, which shall not exceed the cost of such Material as set forth on the Xxxx of Materials plus \*\*\* for each such part and Spare Parts made by Plexus as per the applicable quote plus \*\*\* . Plexus shall only discontinue the supply of a Spare Part as a result of unavailability of such Spare Part from the manufacturer or because a better Spare Part becomes available, and in such event, Plexus shall provide GenMark with the opportunity to make final orders for any discontinued Spare Parts in accordance with Section 2.5.3.5 and shall cooperate with GenMark in connection with any warranty claims related to  
  
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Spare Parts. Plexus shall pass through any and all warranties from the applicable manufacturers of Spare Parts to GenMark. If requested by either party during the term of this Agreement, the parties agree to develop a specific return and repair process for Spare Parts as an amendment to this Agreement.  
  
2.3 Purchase Forecasts. Each month throughout the Term, GenMark shall provide Plexus with a non-binding, rolling forecast specifying the estimated quantity of Products and Spare Parts required by GenMark for the next 12 months on a monthly basis (the “Supply Forecast”). Plexus shall accept or reject the Supply Forecast in writing within \*\*\* of receipt of the Supply Forecast and in the event that no written rejection is received by GenMark within the said \*\*\* the Supply Forecast shall be treated as accepted by Plexus. In the event that the Supply Forecast is properly rejected, the parties shall work together in good faith to agree upon a Supply Forecast that is mutually acceptable within \*\*\* from Plexus’ rejection.  
  
2.4 Product Orders. Orders shall be placed by written purchase order at least \*\*\* prior to the requested Delivery Date and submitted by electronic mail or by other means agreed upon by the parties. Plexus shall accept or reject all orders within \*\*\* following receipt of same and shall deliver all orders that are accepted to the designated location on the date (a) committed to by Plexus in its order acknowledgment, and (b) which shall be no later than \*\*\* days following GenMark’s requested delivery date pursuant to this Section 2.4 (unless a different date is mutually agreed by the parties with respect to volumes in excess of those reflected in Sections 2.5.1(a)-(c)) (the “Delivery Date”). GenMark shall have the right to cancel, without Plexus’ recourse or incurring any costs, expenses or liabilities except for Materials as set forth in Section 2.5.3, any purchase order for which Plexus cannot propose a delivery date within \*\*\* days following the date any order is received, notwithstanding any action taken by Plexus under the applicable purchase order. It is understood that Plexus shall be required to accept orders that are for a quantity of Products and Spare Parts that are reflected in the \*\*\* of each Supply Forecast, and once accepted, such orders are binding and may not be changed by GenMark. If Plexus notifies GenMark of a problem or a potential Supply Failure, GenMark may direct expedited delivery and any increased costs due to expedited delivery shall be paid by and be the liability of Plexus. Any standard printed terms of purchase/sale provided by either party to the other in connection with such purchase and sale shall be disregarded, and the provisions of this Agreement shall govern such purchase and sale and shall supersede and control any additional, conflicting or inconsistent terms or conditions in any such forms.  
  
2.5 Obligation to Supply.   
  
2.5.1 General. Plexus shall accept and fill orders for Products and Spare Parts up to and including (a) \*\*\* of the quantities of Products and Spare Parts set forth in the \*\*\* of each Supply Forecast, (b) \*\*\* of the quantities of Products and Spare Parts set forth in the \*\*\* of each Supply Forecast, and (c) \*\*\* of the quantities of Products and Spare Parts set forth in the \*\*\* of each Supply Forecast. Plexus shall use all commercially reasonable efforts to accept and fill orders for Products and Spare Parts in excess thereof. GenMark acknowledges that repeated requests for upside Product orders beyond any Safety Stock agreed to by the parties may drain the supply chain unless the Forecast is updated in a reasonably timely manner. GenMark acknowledges and agrees that the ability to fulfill quantities in excess of the requirements set forth in this Section 2.5.1 may require Plexus to expedite Materials and GenMark agrees to pay such reasonable expediting fees. Plexus shall fill each purchase order for Products and Spare Parts in whole or in part by using the Safety Stock first (if and to the extent established in writing pursuant to Section 2.6). Any additional Products or Spare Parts required to complete GenMark’s order shall be filled with newly manufactured Products and newly procured Spare Parts.  
  
2.5.2 Alternative Manufacturing Location. Not later than three (3) months following initial delivery of commercial Products hereunder, the parties will work together to identify and develop an actionable plan with respect to a geographically remote Plexus facility as a second source of supply and manufacture for the Products and Spare Parts and to prepare a plan for implementation of production thereof at such second source of supply within a reasonable, agreed period of time (which shall take into account GenMark’s supply needs). In connection with the establishment of such second source of supply, GenMark shall have the right to inspect and qualify such alternative second source and review planning of the new production facility processes and installations and process machinery that would be necessary in the event the plan or certain steps in the plan are executed. Plexus shall in good faith comply with such measures as reasonably requested by GenMark.  
  
2.5.3 Materials. Unless otherwise agreed by GenMark, Plexus shall be responsible for obtaining and shall own and procure directly from the applicable vendors all Materials necessary for the manufacture of the Products. GenMark acknowledges that Plexus may be required by suppliers of Materials or it may be in the parties’ mutual best interests for Plexus to procure Materials in minimum or economic order quantities (“MOQs”) and those quantities may exceed GenMark’s demand for Products as set forth in the Supply Forecasts. In addition, GenMark acknowledges that Plexus may be required by suppliers of Materials to procure the Materials at lead times greater than \*\*\* (“Long Lead Time Materials”). Plexus shall set forth MOQs for Materials on the Xxxx of Materials and GenMark’s written acceptance of the Xxxx of Materials constitutes approval of MOQs. GenMark hereby authorizes Plexus to procure Materials necessary to meet the demand for Products set forth in the \*\*\* of the Supply Forecasts and GenMark’s purchase orders, including Materials solely as necessary to support any increases in quantities  
  
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of Product in excess of the Supply Forecasts as set forth in Section 2.5.1(a)-(c), plus directly associated MOQs and Long Lead Time Materials solely as necessary in support thereof, and agrees to be liable for such Materials in accordance with this Section 2.5.3.  
 2.5.3.1 Material Inventory Reporting. On a quarterly basis or upon GenMark’s request, Plexus will provide GenMark with an inventory report describing in detail the Materials maintained in inventory by Plexus (the “Inventory Report”). GenMark will respond to Plexus in writing within \*\*\* of receipt of the Inventory Report with any good faith disagreement to it, detailing with reasonable particularity the nature of any such disagreement. GenMark’s failure to respond within such period will represent its acceptance of the Inventory Report. In the event GenMark disagrees with the Inventory Report, GenMark and Plexus will work in good faith to promptly resolve the disagreement, escalating such disagreement to executive management at the request of either party. Any undisputed portion of the Inventory Report shall be resolved pursuant to Sections 2.5.3.2 and 2.5.3.3.  
  
2.5.3.2 Aged Material Inventory Resolution. “Aged Material” means any Material procured by Plexus in accordance with Section 2.5.3 that remains in Plexus’ inventory for \*\*\* or longer for reasons other than Plexus’ failure to manufacture and deliver Products in accordance with GenMark’s purchase orders issued in accordance with this Agreement and the Supply Forecast (and then only to the extent such Material is directly related to the failure to manufacture or deliver), unless such failure to manufacture and deliver is due solely to GenMark’s request to delay timely delivery. For all Aged Materials, GenMark shall, upon Plexus’ demand, elect one of the following options: (a) provide Plexus with a purchase order for Products that will consume such Aged Material within \*\*\* , (b) pay Plexus a cash deposit in the amount of the cost of such Material as set forth on the Xxxx of Materials, plus an amount equal to the Applicable Materials Overhead Percentage multiplied by such cost, such deposits to be reconciled quarterly, or (c) pay to Plexus a monthly inventory management fee in an amount equal to \*\*\* of the cost of such Material as set forth on the Xxxx of Materials, plus an amount equal to the Applicable Materials Overhead Percentage multiplied by such cost. In addition, for Aged Materials held by Plexus for more than \*\*\* , GenMark shall purchase such Aged Materials from Plexus upon written demand at a price equal to the cost of such Material as set forth on the Xxxx of Materials, plus an amount equal to the Applicable Materials Overhead Percentage multiplied by such cost. For purposes of this Agreement, the “Applicable Materials Overhead Percentage” shall equal the materials overhead percentage set forth in the current Product pricing for the applicable pricing tier based on the pricing tiers in effect as of the date of determination.  
  
2.5.3.3 Obsolete Material Inventory Resolution. “Obsolete Material” means any Material procured by Plexus in accordance with Section 2.5.3 that is removed by GenMark from the Xxxx of Materials or remains on the Xxxx of Materials but has no demand for consumption of the Material within the next \*\*\* . For all Obsolete Materials, GenMark shall provide instructions to Plexus to either ship or scrap the Obsolete Materials and issue a purchase order for such Obsolete Materials to Plexus within \*\*\* after receiving written notice from Plexus, upon which Plexus shall invoice GenMark for the cost of such Material as set forth on the Xxxx of Materials, plus an amount equal to the Applicable Materials Overhead Percentage multiplied by such cost. GenMark shall be responsible for any reasonable direct out-of-pocket costs or expenses associated with the scrapping of Materials under this Section 2.5.3.3.  
  
2.5.3.4 Material Inventory Mitigation. Plexus shall use all commercially reasonable efforts to minimize and mitigate Material liability for Aged Materials and Obsolete Materials, which shall include returning Materials to, or restocking Materials with, suppliers of Materials, canceling orders with suppliers of Materials, or using such Materials to satisfy the current demand of Plexus’ other customers. GenMark agrees to assist Plexus in such efforts if appropriate and requested by Plexus. GenMark acknowledges that Plexus’ mitigation efforts, even if successful, may result in cancellation, restocking, and similar charges imposed by suppliers of Materials. Plexus shall obtain GenMark’s written approval prior to incurring such charges. If so approved by GenMark, GenMark shall pay Plexus for the charges imposed in accordance with Section 2.9.  
  
2.5.3.5 Material and Spare Part Last Time Buys. Plexus shall notify GenMark as soon as practicable after receiving notice from manufacturers that a Material or Spare Part is going end-of-life. At GenMark’s request, Plexus shall coordinate a last time buy of end-of-life Materials or Spare Parts and hold such Materials or Spare Parts in Plexus’ inventory for use in manufacturing Products or for Spare Part sales hereunder. Immediately upon receipt into Plexus’ inventory, last time buy purchases of Materials or Spare Parts that are not covered by the \*\*\* of GenMark’s most recent Supply Forecast shall be considered Aged Inventory and GenMark shall issue a cash deposit to Plexus or pay an inventory management fee in respect of such Material or Spare Parts to Plexus in accordance with Section 2.5.3.2.  
  
2.5.3.6 Material Invoicing. Invoices under this Section 2.5.3 shall be paid in accordance with Section 2.9.  
  
2.5.4 Vendor Arrangements. Plexus shall establish appropriate contracts with suppliers of raw or key Materials and shall exercise commercially reasonable efforts to ensure stability of, and long-term pricing for, Material supply.  
  
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\*\*\* Portions of this page have been omitted pursuant to a request for Confidential Treatment and filed separately with the Commission.   
  
Plexus shall implement and, as necessary, update inventory management processes and procedures reasonably designed to ensure that Plexus has on hand, when necessary, sufficient Materials to manufacture, supply and deliver Products hereunder. Plexus shall use vendors for Materials used in the manufacture of the Products as directed or agreed to by GenMark, and shall not use any Materials or Material suppliers not approved by GenMark for the manufacture of the Products.  
  
2.5.5 Supply Failure. Plexus shall communicate regularly with GenMark during the term of this Agreement regarding Plexus’ ability to meet GenMark’s Supply Forecast requirements and will promptly advise GenMark in writing of any anticipated Supply Failure event explaining the nature, impact and estimated duration of the Supply Failure event. Plexus shall use all commercially reasonable efforts to remedy the Supply Failure within a reasonable time at no additional cost to GenMark. If Plexus is unable to remedy the Supply Failure within \*\*\* after the start of the Supply Failure event, then Plexus shall consult with GenMark and the parties shall work together to remedy the Supply Failure, which the parties acknowledge may include formally commencing Product manufacturing activities at the alternative manufacturing location identified pursuant to Section 2.5.2. Plexus hereby agrees to allow GenMark to provide such reasonable assistance to Plexus as the parties may deem necessary to avert or minimize any Supply Failure, including, without limitation, to sourcing or manufacturing with third parties’ parts or raw materials that are in short supply; provided, however, that Plexus will not unreasonably refuse such offers of assistance by GenMark and GenMark will have no obligation or duty to offer such assistance. If Plexus is unable to remedy the Supply Failure, after an aggregate period of \*\*\* (or longer as agreed in writing by the parties), commencing with the date upon which such Supply Failure event began, then GenMark may at its option immediately terminate this Agreement upon written notice to Plexus.  
  
2.6 Safety Stock. The Parties commit to diligently work together to develop the most appropriate supply chain model for the supply of Products and Spare Parts hereunder to support GenMark’s Product supply and stocking needs. In the event safety stock of finished goods Products or of Materials held by Plexus is part of the agreed upon supply chain model, the consent to which shall not be unreasonably withheld by Plexus, the parties will agree to a quantity of safety stock to be held by Plexus and any associated costs in respect thereof prior to GenMark’s first commercial sale of a Product (the “Safety Stock”). This Safety Stock shall remain separate and distinct from inventory held at the Facility and shall be stored by Plexus. Plexus will use Safety Stock to supply Products ordered by GenMark hereunder, and will maintain the appropriate level of Safety Stock by promptly replenishing that quantity of Products used in such supply. Plexus will manage Safety Stock on a “first in, first out” basis to fulfill GenMark’s purchase orders on a routine basis. Plexus shall use all commercially reasonable efforts to replenish its Safety Stock within \*\*\* of use. GenMark shall purchase any Products remaining in Safety Stock for \*\*\* or longer upon written demand from Plexus. Plexus shall within \*\*\* of the end of the Replenishment Period notify GenMark in writing of its inability to replenish the Safety Stock as required herein.  
  
2.7 Use of Subcontractors. Plexus shall not subcontract or otherwise use any third party for the performance of its obligations hereunder without GenMark’s prior written consent. If GenMark consents to any subcontract or third party involvement hereunder, (a) the subcontractor or third party shall be required to enter into an agreement containing (i) confidentiality terms that are at least as restrictive as those in Article VII hereof and (ii) provisions for the assignment of inventions and intellectual property rights arising from the subcontracted work necessary and appropriate to effect the provisions of Article VI, and (b) Plexus shall supervise the work of any such subcontractor or other third party to ensure that the subcontractor’s or other third party’s work is in full compliance with all requirements of the Manufacturing Documents, the terms of this Agreement, and the Applicable Standards. Plexus shall remain responsible for any activities performed hereunder by any permitted subcontractor as if such activities were performed by Plexus.  
  
2.8 Product Price.   
  
2.8.1 Initial Pricing. The (a) price for beta versions of the Products, and (b) the pricing criteria which the parties shall use to establish initial production Product pricing at particular annual volumes of manufacture and Spare Parts (the “Pricing Criteria”), in each case is identified on Exhibit C. The initial prices for production Products shall be established and agreed to in writing by the parties in accordance with the Pricing Criteria prior to any purchase of production Products hereunder. Production Product pricing shall be reviewed regularly and adjusted as provided for herein.  
  
2.8.2 \*\*\* Pricing Determination. Pricing for the Product Material line item only shall be re-quoted based on pricing tiers and mutually agreed \*\*\* ; provided that any and all other line items comprising Product pricing then in effect shall remain unchanged on a per-tier basis (which, to the extent such line items are calculated as a percentage of other Product pricing line items or a percentage of the aggregate Product cost, shall not exceed the percentages then in effect with respect to such tier). Prices applicable to individual purchase orders shall be initially determined based on the total quantity of Products forecast by GenMark on the Effective Date for Product purchases occurring between the Effective Date and December 31, 2015, and thereafter shall be based on GenMark’s Product purchase estimates for \*\*\* during the term of this Agreement (each such \*\*\* forecast, \*\*\* “ \*\*\* Supply Forecast”). GenMark shall provide the \*\*\* Supply Forecast to Plexus no later than \*\*\* of each \*\*\* during the term and Plexus shall respond with a pricing quotation for Products no later than \*\*\* after  
  
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receipt of the \*\*\* Supply Forecast.  
  
2.8.3 \*\*\* Pricing Tier Review. No later than \*\*\* during the term, the Parties will conduct a \*\*\* pricing review and adjust pricing for the remainder of the calendar year if \*\*\* Volume calculated as of \*\*\* means a different price tier applies. “ \*\*\* Volume” means the sum of (a) Product shipments occurring between \*\*\* and \*\*\* (which shall include any shipments not made during such period as a result of Force Majeure or Plexus’ failure to fulfill Product orders submitted in accordance with this Agreement by the applicable Delivery Date), (b) the volume of Products in transit, if any, (c) the volume of Products in the current Forecast for the remainder of \*\*\* , and (d) the volume of Products in open purchase orders if such quantities are not reflected in such Forecast or are already in transit.  
  
2.8.4 Pricing Adjustment Events. The parties shall review and agree to new pricing at the request of either party in the event the party making such request can reasonably demonstrate (a) changes to Products, Specifications, Testing Criteria, or additional GenMark requirements have directly impacted Product manufacturing or Material costs, or (b) market-driven Material cost fluctuations exceeding \*\*\* of the aggregate Materials cost line item of the current price have persisted for at least \*\*\* despite Plexus’ commercially reasonable efforts to reduce or eliminate such price fluctuations (each, a “Pricing Adjustment Event”). Upon any such request by Plexus, Plexus shall promptly deliver to GenMark such documentation as reasonably requested by GenMark, consistent with past practice, to verify any purported cost increase related to the particular Pricing Adjustment Event. Within \*\*\* of such request and the parties’ receipt of reasonably sufficient verification demonstrating an actual associated price increase has been incurred in respect of the particular Pricing Adjustment Event, the parties shall in good faith review the impact of such unforeseen circumstances and, if appropriate, agree on updated pricing solely to reflect the allocation of any agreed upon price increases resulting directly from the particular Pricing Adjustment Event, which shall be implemented on the date agreed by the parties. On the day any new pricing is implemented, Plexus will also write-down or write-up, as applicable, existing Materials on hand or on order held by Plexus to reflect the new agreed pricing and invoice or credit GenMark for such adjustment, as applicable. The parties agree to close any financial claims within \*\*\* of the effective date of any pricing adjustment implemented pursuant to this Section 2.8.4.  
  
2.8.5 Continuous Process Improvements. The parties acknowledge and agree that they will work together to identify, design and implement continuous Product and process improvements (“CPIs”) that aim to reduce Material costs and Plexus’ own internal costs to achieve cost savings, which the parties agree shall include the detailed assessment of potential lower cost alternative manufacturing locations. Every \*\*\* during the term of this Agreement, Plexus shall prepare and deliver to GenMark a written report describing (a) proposed CPI projects and plans and related expected cost savings to be achieved upon implementation of such measures, and (b) the labor and Material cost savings (including labor cost reductions due to decreased labor for inspection and instrument xxxxxxx requirements) achieved by Plexus due to the implementation of CPIs (“CPI Cost Savings”). CPI Cost Savings shall target at least a \*\*\* cost reduction each year over the pricing then in effect. Plexus shall in good faith consult with GenMark in establishing its CPI plans hereunder and shall implement all reasonable CPI Cost Savings opportunities reasonably requested by GenMark. The parties will agree on a process for reviewing CPI plans, the appropriate tool set for managing CPI initiatives as they are implemented, and any relevant communication plans or reporting, including an appropriate process for tracking, validating, and demonstrating the nature and amount of CPI Cost Savings. The benefit of any CPI Cost Savings shall (i) first, be immediately allocated to the party incurring the out-of-pocket expenses, if any, to implement the CPI Cost Savings, until such party is reimbursed for such expenses, (ii) second, provided that such CPI Cost Savings opportunity was first identified by Plexus, the parties shall thereafter immediately split such savings \*\*\* for \*\*\* after the reimbursement of expenses pursuant to subsection (i), and (iii) thereafter (or if GenMark first identifies such CPI Cost Savings opportunity), one hundred percent (100%) of the CPI Cost Savings shall be passed on to GenMark immediately.  
  
2.8.6 Meetings. Representatives of both parties shall meet at least once each calendar quarter during the term of this Agreement and shall meet at such other times as deemed appropriate by either party. Representatives of each party attending such meetings must be appropriate for the tasks then being undertaken, in terms of their seniority, availability, and function in their respective organizations, training and experience. The purpose of such meetings is to serve as a venue for the parties to provide timely notice of their respective expectations for the next twelve (12) months, review CPI Costs Savings plans, execution, and realized savings (including in respect of Product manufacturing yield and its related impact on labor rates), as well as trends and developments they foresee in order to reduce the likelihood of surprises with respect to GenMark’s demand for Products or Plexus’ pricing for Products. Such representatives may meet in person or via teleconference, video conference or the like, provided that at least one (1) meeting every six (6) months shall be held in person. If meetings are held in person they shall be held at either the headquarters of Plexus or the headquarters of GenMark on an alternating basis, unless the parties mutually agree to hold such meeting in an alternative venue. Each party shall bear the expense of its respective representatives’ participation in such meetings. The parties shall review and approve on a timely basis the expected forecasts for Products and the proposed pricing for Products for the next contract year. In the event that Plexus does not approve GenMark’s expected forecast for Products or GenMark does not approve Plexus’ proposed pricing for any Product(s) as presented at the meeting, then such party shall provide the other party with a detailed statement describing the basis of its concerns and the parties shall in good faith seek to resolve  
  
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such matter prior to the commencement of the next calendar year in accordance with the provisions of this Agreement.  
  
2.9 Invoicing. Plexus shall submit invoices to GenMark for all shipments of Products hereunder upon shipment of such Products. The invoices shall reference GenMark’s purchase order number and shall contain such other information as GenMark may reasonably request. GenMark shall pay any undisputed invoices for Products by electronic funds transfer within \*\*\* after the date of receipt of Plexus’ invoice. All payments shall be stated and paid in United States Dollars. GenMark shall report any believed discrepancies in Plexus' invoices no later than \*\*\* after receipt of invoice. Undisputed invoices not paid within \*\*\* of their due date will be subject to an interest charge equal to the lesser of \*\*\* or the highest rate allowed by law.  
  
2.10 Payment Disputes. In the event GenMark desires to dispute any item(s) under any invoice, GenMark will provide Plexus within \*\*\* after delivery of the invoice with written notice setting forth the details of the disputed item(s) and the amount in question. GenMark will timely pay to Plexus all undisputed amounts on any such invoice. The parties will work together, in good faith, to resolve such dispute within \*\*\* after such notice of dispute is sent. If the parties are unable to resolve a dispute within such \*\*\* period, the parties shall escalate such dispute for resolution pursuant to the provisions of Section 10.1 hereof. Despite any such escalation, Plexus shall not cease, postpone or terminate performance of its activities hereunder while such dispute is being resolved. GenMark’s failure to pay the portion(s) of an invoice that it disputes in good faith using the procedure specified in this Section 2.10 shall not constitute a material breach under this Agreement.  
  
2.11 Payment of Taxes. In addition to the prices quoted or invoiced, GenMark agrees to pay any taxes, duties or fees properly assessed on the Products, excluding any taxes on Plexus’ income. In the event Plexus is required to pay such tax, duty or fee, GenMark shall reimburse Plexus within \*\*\* of written demand. If the transaction between Plexus and GenMark is exempt from all such taxes, duties and/or fees, GenMark shall provide Plexus with a tax exemption certificate or other document acceptable to the applicable authorities at the time the Purchase Order is placed.  
  
2.12 Shipping. Products ordered by GenMark shall be shipped by Plexus FCA Plexus’ manufacturing site for all shipments. Title to Products shall pass to GenMark when the Products are placed in the hands of the carrier at the shipping point.  
  
2.13 Labelling. Plexus will supply Products to the locations designated by GenMark in finished and final packaged format for end user sale (including all trade dress, labeling and warning and handling instructions), as documented in the applicable Specifications for each Product. GenMark is solely responsible for specifying and validating finished device packaging and other packaging requirements, including any unique device identifier requirements, and for determining the content of any labeling, warning or handling instructions. Plexus shall label all Products in accordance with the Specifications and shall affix on each Product all regulatory compliance symbols that GenMark directs Plexus to affix on the Products or as otherwise set forth in the Specifications, including, but not limited to, the CE xxxx, and UL and/or CSA, RoHS and WEE symbols. GenMark is solely responsible for obtaining and maintaining the right to affix such regulatory compliance symbols on GenMark’s Products. GenMark shall provide Plexus with Product labeling artwork or graphics as necessary for Plexus to comply with this Section 2.13.  
  
2.14 Acceptance and Rejection.   
  
2.14.1 General. Each Product shipment shall contain such quality control certificates as are necessary to demonstrate that the Product is in conformity with the Specifications and Testing Criteria, including a Certificate of Conformance (“COC”) in the form agreed to by the parties. GenMark shall notify Plexus within \*\*\* of delivery of a shipment of the Product of any apparent non-conformity of the Product to the Specifications. If GenMark fails to so notify Plexus, it will be deemed to have accepted the Product; provided that the warranties contained in Section 5.2 and Plexus’ obligations under Section 8.1 shall survive acceptance of the Product by GenMark.  
  
2.14.2 Release Testing. Plexus shall perform all in-process and finished Product tests or checks required by the Testing Criteria. For purposes of this Agreement, such tests are included in the price of the Products. All tests and test results shall be performed, documented and summarized by Plexus in accordance with the Testing Criteria and the Applicable Standards. Plexus shall immediately notify GenMark in writing of any significant out of specification testing results for either in process or finished Product test results.  
  
2.14.3 Rejection. Plexus shall at its expense and at no further cost to GenMark repair or replace any Products that do not conform to the Specifications due to a failure of the Products to conform to the warranties provided by Plexus in Section 5.2. All defective units of the Product shall be returned to Plexus at Plexus’ cost. In the event that GenMark notifies Plexus in writing of its rejection of Product under this Section 2.14, GenMark shall request a Return Material Authorization (“RMA”) number which shall be provided by Plexus as soon as reasonably practicable (but in any event within \*\*\* ) and GenMark shall within \*\*\* of receipt of such RMA number return such rejected Product to Plexus at Plexus’ expense. Plexus shall use all  
  
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reasonable commercial endeavors to test the rejected Product promptly and in any event shall do so within \*\*\* of receipt of such rejected Product. In the event Plexus determines in good faith that the Product was properly rejected by GenMark, Plexus shall, at Plexus’ election, repair or replace such defective Product within fifteen (15) business days of such determination or, \*\*\* . In the event that any rejected Product is determined by Plexus in good faith to not be properly rejected, and GenMark accepts such determination, such acceptance not to be unreasonably withheld, GenMark shall reimburse Plexus for all costs and expenses related to the return of such Product to GenMark. If there is disagreement between the parties as to whether any Product was properly rejected, the parties shall have such Product tested by a mutually agreed upon third party and such third party’s determination as to whether such Product was properly rejected shall be binding on the parties. The expense for such testing shall be borne by Plexus unless it is determined that the Product in question was not properly rejected, in which case the expense shall be borne by GenMark.  
  
2.14.3.1 Within Warranty Repair. Plexus will be responsible for (a) the shipping, delivery and insurance costs associated with the return and/or replacement of any Product which does not satisfy the warranties set forth in Section 5.2 of this Agreement (each, a “Warranty Non-Compliant Product”); (b) all costs and expenses incurred by or on behalf of Plexus or its Affiliates in connection with the repair, replacement or service of any Warranty Non-Compliant Product; \*\*\* .  
  
2.14.3.2 No Fault Found Returns. Where a Product is returned to Plexus as being Warranty Non-Compliant but Plexus demonstrates (with supporting documents) to GenMark’s reasonable satisfaction that the Product complies with the warranties set forth in Section 5.2 (each, a “Warranty Compliant Product”), then Plexus’ investigation and Product (re)qualification costs will be charged to GenMark at Plexus quoted cost, which shall be reasonable and consistent with past practice, plus markup not to exceed \*\*\* , subject to generating and providing GenMark with a quotation for such costs, and the Product will be returned to GenMark, with GenMark covering return shipping, delivery and insurance costs.  
  
2.14.4 Shortages. GenMark shall notify Plexus in writing of any shortage in quantity of any shipment of Product within \*\*\* of receipt of such Product. In the event of such shortage, Plexus shall use its reasonable efforts to make up and ship the shortage as promptly as possible, but with the substitute shipment occurring no later than \*\*\* after notice, at no additional cost to GenMark other than the price of the Products.  
  
2.15 Intentionally Omitted.  
  
2.16 Service and Repair. All service and repair activities (whether covered or not by the warranty given by Plexus pursuant to Section 5.2) requested of Plexus by GenMark will be performed by Plexus at the Facility (or such other location as approved in writing by GenMark) under an RMA number, and shall be completed promptly and without delay but in no event later than \*\*\* after Plexus receives the Product at issue, unless some other time period is set forth in a statement of work or proposal for service or repair activities. Serviced or repaired Products shall be warranted by Plexus until the date that is the later of: (a) the end of the original warranty period under Section 5.2 for the Product at issue; or (b) \*\*\* after the date the repaired Product is delivered by Plexus to GenMark. Plexus will send a quotation to GenMark and shall get GenMark’s written consent to the quotation before starting any service or repair on any Warranty Compliant Product. With respect to any particular service or repair of a Warranty Compliant Product for which GenMark provides its written consent as provided above in this Section, Plexus will promptly proceed with such service or repair. GenMark will not be responsible for any such cost for service or repair of Warranty Non-Compliant Products. Plexus will provide a quality release document with each returned serviced and repaired Product. At GenMark’s option and upon GenMark’s request, Plexus will make available to GenMark, at GenMark’s expense, the necessary documents, programs and Product-specific tools (or other tools to the extent not maintained by Plexus as trade secrets under applicable law) to allow GenMark to perform service and repair on Products at GenMark’s premises and/or at customers' sites. Within sixty (60) days of the Effective Date, the parties agree to develop a comprehensive Product and Spare Parts service, repair and technical support program, which shall include GenMark Field Service as agreed by the parties in good faith.  
  
ARTICLE III  
REGULATORY AND QUALITY ARRANGEMENTS  
3.1 Regulatory Approvals. GenMark shall perform and be responsible at its sole cost and expense for any clinical trials and regulatory activities that may be required to commercialize the Products (collectively, the “Regulatory Approvals”). GenMark shall have the exclusive right to determine in its sole discretion the strategy for Regulatory Approvals, including where and how to gain Regulatory Approvals. GenMark shall be the sole and exclusive owner of all right, title and interest in and to all Regulatory Approvals.  
  
3.2 Cooperation. Plexus shall cooperate with GenMark in obtaining and maintaining such Regulatory Approvals as requested by GenMark, including through the furnishing of information required for Regulatory Approvals and submitting, if required, to regulatory audits and inspections by Governmental Authorities at the Facility. Plexus shall provide any Confidential Information that is required by a Governmental Authority in support of Regulatory Approvals and/or Product compliance either  
  
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to GenMark or directly to the requesting Governmental Authority.  
  
3.3 Regulatory Compliance. Plexus shall manufacture and produce Products hereunder, and maintain all necessary documentation and information in respect of such activities, including any Manufacturing Documents to be maintained by Plexus as agreed to by the parties, in each case in accordance with the Applicable Standards.  
  
3.4 Rights of Monitoring, Inspection and Audit. Upon at least seven (7) days advanced notice and at a mutually agreeable time during normal business hours, GenMark shall have the right to have its representatives onsite at the Facility as part of its regular monitoring of the manufacturing activities to be conducted hereunder and/or to visit the Facility to conduct evaluations of Plexus’ performance under this Agreement and its compliance herewith, in each case at GenMark’s discretion. Plexus shall require that all approved agents or subcontractors hereunder shall grant GenMark reasonable access to their facilities and records to conduct evaluations of their performance under this Agreement and its compliance herewith. Plexus agrees to provide GenMark with access to such records and personnel as reasonably requested by GenMark for such purposes, including Plexus’ quality control, testing, manufacturing, design records and other records and information reasonably related to the performance of its manufacture of the Products.  
  
3.5 Regulatory Inspections. Plexus agrees to inform GenMark within twenty-four (24) hours of notification of any regulatory inquiry, communication or inspection, which reasonably relates to the manufacture of the Products or could impact Plexus’s ability to manufacture or supply the Products. GenMark, at its option, shall have the right to have its representatives present at any such inspection by a Governmental Authority. In the event there are written observations (or any other written communication) by a Governmental Authority that involves any Product or could impact Plexus’ ability to manufacture or supply any Product, or any proposed written response by Plexus to any such inspection or inquiry, Plexus will use reasonable efforts to provide GenMark with copies of all documentation prior to submission to the applicable Governmental Authority and shall have the opportunity to review and comment on the proposed response. If GenMark elects to provide input to the response, such input shall be provided by GenMark as promptly as possible and Plexus shall in good faith consider such input. Nothing herein shall limit GenMark’s right to respond directly to any Governmental Authority if any questions are directed to GenMark.  
  
3.6 Incidents or Accidents. Plexus shall immediately notify GenMark in writing of any incident or accident experienced by Plexus that may affect the quality of the Products or its ability to timely perform its obligations hereunder. Such incident or accident shall be immediately investigated by Plexus, and Plexus shall provide a written report within \*\*\* business days of the results of the investigation of such incidence or accident to GenMark.  
  
3.7 Quality Assurance. The parties shall comply with the terms of the Quality Agreement in the performance of their activities hereunder. Prior to shipping any Product, Plexus will carry out the Product tests specified in the Testing Criteria. If any Product fails to meet such requirements, such non-conformance shall be handled in accordance with the Manufacturing Documents or as otherwise directed by GenMark. No Product will be shipped to GenMark or its designee without passing all tests specified in the Manufacturing Documents, except with GenMark’s prior written approval. Plexus will maintain manufacturing quality documentation, including records of its Product tests, in accordance with the Applicable Standards.  
  
3.8 Product Changes. Plexus shall not make any change to any Product’s design, manufacturing process, Materials, Material suppliers or components without GenMark’s prior written approval. If any such changes to the Products are authorized in writing by GenMark, such changes must comply with the terms of the Quality Agreement. Upon GenMark’s request, Plexus agrees that it will facilitate all changes to the Specifications that are necessary or appropriate under applicable laws, as determined by GenMark, or GenMark’s performance requirements and GenMark shall update the Specifications accordingly and communicate the changes in writing to Plexus. Plexus shall exercise all commercially reasonable efforts to implement any changes to the Products approved by GenMark hereunder as soon as reasonably practicable, but in any event within \*\*\* from the date of GenMark’s written approval thereof. “Engineering Change” means modifications to the Specifications by GenMark that (1) affect the form, fit, function, delivery schedule, performance, reliability, appearance, dimensions, tolerance, safety or purchase price of such Products or (2) require additional or modified Testing Criteria. GenMark agrees to submit all Engineering Changes to Plexus in writing. Plexus will use commercially reasonable efforts to respond to GenMark within \*\*\* with a written evaluation of the Engineering Change including: (a) the administrative cost to implement the Engineering Change; (b) the cost to modify GenMark Equipment or related non-recurring expenses; (c) the quantity of Materials that will become Obsolete Materials due to the Engineering Change; (d) the cost to rework work-in-progress Products; (e) any Product price adjustment resulting from the Engineering Change; (f) the expected effect on the delivery schedule; and (g) the manner in which the Engineering Change will be implemented.  
  
3.9 Reserved.  
  
3.10 Change Control. Plexus shall establish and maintain an effective and compliant Change Control for changes to  
  
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the design of the Products in accordance with the Manufacturing Documents and GenMark’s instructions.  
  
3.11 Vigilance. Plexus shall promptly notify GenMark if it becomes aware of any information about the Products indicating that it may not conform to the Specifications or otherwise perform as intended. The parties will promptly confer to discuss such circumstances and to consider appropriate courses of action. In the event that (a) an event, incident, or circumstance may result in the need for a removal of any Product or any lot or lots thereof from the market or any regulatory reportable event occurs which is attributable to the Product, (b) any Governmental Authority threatens to prohibit the use of any Product as a result of a defect of the Product, or (c) any Governmental Authority requires distribution of a “Dear Doctor” letter or its equivalent regarding the use of any Product, in each case the parties shall promptly advise each other in writing, and shall provide each other with copies of all relevant correspondence, notices and the like. Notwithstanding anything to the contrary herein, GenMark shall have final authority to make all decisions relating to corrective and/or preventive action with respect to Products. Internal investigation of any such event will take place promptly after the parties become aware of the reportable event and the root cause and appropriate remedial measures will be determined and documented to the best of the parties’ capabilities. GenMark or its designee will make all contacts with any Governmental Authorities in respect of any event described in this Section 3.11 and will be responsible for coordinating all of the necessary activities in connection with such action. Plexus will cooperate with GenMark in the conduct of any such activities. Notwithstanding anything to the contrary herein, GenMark is solely responsible for all complaint handling, including, without limitation, maintenance of complaint files, investigation and resolution of complaints, trend analysis of complaints, and maintenance of complaint-related records. GenMark is solely responsible for FDA medical device reporting obligations under 21 CFR Part 803 and similar reporting regulations in jurisdictions outside the United States. GenMark shall promptly provide to Plexus copies of all written complaints of any Governmental Authority received by GenMark that relate to any Product. Plexus shall provide to GenMark information regarding any complaints Plexus receives about the Products.  
  
3.12 Reliability Requirements. During the term hereof, the parties agree to cooperate in good faith with each other and provide such data and information, including service and reliability data, statistics and analyses relating to failure rates, failure mechanisms and repair times to one another on a quarterly basis or as otherwise reasonably requested by either party as necessary or appropriate to determine whether and to what extent the Products satisfy GenMark’s reasonable reliability requirements (which shall be consistent with industry standards). All such information shall be subject to the confidentiality provisions of Article VII hereof. If one or more Product(s) fails to achieve such reliability requirements during the term hereof, the parties agree to mutually perform an analysis to determine the root cause(s) for such failure(s).  
  
3.13 Program Material. Within \*\*\* of a written request received from GenMark, Plexus shall provide GenMark with complete and current copies of all Program Material requested by GenMark.  
  
3.14 Decontamination Prior to Return of Products. GenMark shall ensure that all Products are decontaminated in accordance with a mutually agreed-upon decontamination process prior to shipment to Plexus for repair or other services and that all appropriate documentation and/or certification of such decontamination accompanies the Products.  
  
3.15 Material Traceability. GenMark is responsible for identifying critical Materials that require component level traceability. GenMark shall select the appropriate component level or device level traceability grade, in order to meet any applicable regulations or requirements of Governmental Authorities.  
  
3.16 Software Validation. GenMark is responsible for the validation of any software embedded in the Products and the validation of all GenMark-supplied: (1) test equipment or software; (2) production equipment or software; and (3) firmware. Plexus is responsible for the validation of any Plexus software used in production or as part of the Plexus quality system.  
  
ARTICLE IV  
EQUIPMENT  
  
4.1 GenMark Equipment. GenMark and Plexus shall maintain accurate books and records of all GenMark Equipment. A preliminary list of the GenMark Equipment is set forth on Exhibit D hereto. The parties shall maintain an updated list of GenMark Equipment to be used at the Facility throughout the term of the Agreement. GenMark shall at all times hold exclusive title to the GenMark Equipment and may assign, transfer, pledge or sell its interest in the GenMark Equipment without notice to or approval from Plexus. Plexus shall exercise due care and hold, store and protect the GenMark Equipment at the Facility as a bailee during the term of this Agreement, subject to the terms and conditions contained herein. All GenMark Equipment shall be physically segregated at the Facility from all other inventory, products, material, equipment or other personal property of Plexus or any third party and shall be clearly labeled at the Facility and within Plexus’ books and records as the “Property of GenMark Diagnostics, Inc.” Plexus shall not use the GenMark Equipment for its own benefit or for the benefit of any third party, nor shall Plexus use the GenMark Equipment for any other purpose other than manufacturing Products hereunder. GenMark shall have the right at any time to inspect the GenMark Equipment to ensure Plexus’ compliance hereunder. In the event Plexus procures equipment  
  
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on GenMark’s behalf, title to the equipment shall pass to GenMark when Plexus receives payment in full for the equipment, at which time, such equipment shall become GenMark Equipment. Plexus shall provide general/routine maintenance of GenMark Equipment at no charge during the term of this Agreement. Upon GenMark’s request or per GenMark Equipment maintenance instructions, Plexus shall provide specific maintenance, repair, calibration, or upgrade services at GenMark’s expense on a time and materials basis. Plexus shall notify GenMark in advance and obtain the written agreement of GenMark with respect to any such specific maintenance, repair or calibration prior to taking such action. Replacement parts for GenMark Equipment will be charged at Plexus’s cost plus quoted markup not to exceed \*\*\* .  
  
4.2 Protection of GenMark Equipment. Plexus shall not make available or purport to sell, lease or convey to any third party or permit any third party to assert or attach any liens on or against the GenMark Equipment, nor shall Plexus, by agreement or otherwise, use the GenMark Equipment as collateral in any secured transaction or perfect any security interest in the same or otherwise encumber the GenMark Equipment. Plexus shall execute such other instruments and other assurances as GenMark may request in order to confirm and protect GenMark’s exclusive ownership of the GenMark Equipment. Plexus agrees that if any third party attempts to claim ownership of the GenMark Equipment by asserting a claim against Plexus or through Plexus, Plexus will take all actions necessary or useful to permit GenMark to protect its title to the GenMark Equipment, including, without limitation, executing any documents or powers-of-attorney as reasonably necessary to accomplish the same.  
  
4.3 Unconditional Right to Remove GenMark Equipment. GenMark shall have the unconditional right to remove and reclaim the GenMark Equipment from the Facility at any time and for any reason whatsoever upon written notice to Plexus, and Plexus shall provide all assistance necessary or useful to permit GenMark to remove the GenMark Equipment from the Facility. If GenMark’s request for the return of GenMark Equipment materially adversely impacts Plexus’s ability to perform its obligations under this Agreement, Plexus shall be relieved from all obligations under this Agreement which require access to and use of such GenMark Equipment.  
  
ARTICLE V  
REPRESENTATIONS AND WARRANTIES  
  
5.1 Mutual Representations and Warranties. Each of GenMark and Plexus hereby represents and warrants as of the Effective Date (except as specifically otherwise indicated below) as follows:  
  
5.1.1 Corporate Existence and Power. Such party: (a) is a corporation duly organized, validly existing and in good standing under the laws of the state in which it is incorporated; (b) has the corporate power and authority and the legal right to own and operate its property and assets, to lease the property and assets it operates under lease, and to carry on its business as it is now being conducted; and (c) is in compliance with all requirements of applicable law, except to the extent that any noncompliance would not have a material adverse effect on the properties, business, financial or other condition of such party and would not materially adversely affect such party’s ability to perform its obligations under this Agreement.  
  
5.1.2 Authorization and Enforcement of Obligations. Such party: (a) has the corporate power and authority and the legal right to enter into this Agreement and to perform its obligations hereunder; and (b) has taken all necessary corporate action on its part to authorize the execution and delivery of this Agreement and the performance of its obligations hereunder. This Agreement has been duly executed and delivered on behalf of such party, and constitutes a legal, valid and binding obligation, enforceable against such party in accordance with its terms.  
  
5.1.3 Consents. All necessary consents, approvals and authorizations of all Persons required to be obtained by such party in connection with the execution of this Agreement have been obtained on or before the Effective Date.  
  
5.1.4 No Conflict. The execution and delivery of this Agreement and the performance of such party’s obligations hereunder (a) do not conflict with or violate any requirement of applicable laws or regulations, and (b) do not conflict with, or constitute a default under, any material contractual obligation of such party.  
  
5.2 Plexus’ Manufacturing Warranties.  
  
5.2.1 General. Plexus warrants to GenMark that for a warranty period of \*\*\* after the date of delivery (a) all Products shall be manufactured, processed, labeled, packaged, stored and tested in accordance with the Manufacturing Documents, and the terms of this Agreement, (b) that all Products supplied hereunder shall be manufactured in conformance with the Specifications, (c) that it will convey good title to each Product shipped under this Agreement, (d) each Product will be delivered free from any security interest, lien or encumbrance, and (e) the Products shall be free of any defects in workmanship. Plexus shall exercise its \*\*\* to obtain warranty rights from suppliers of Material consistent with the warranties provided by Plexus herein, and pass through or assign to GenMark such warranty rights, to the extent that such rights are able to be passed through or assigned.  
  
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In the event of a non-conformance in Materials, Plexus shall coordinate with and be the point of contact for resolution of the problem through the applicable supplier and, upon becoming aware of the problem, will notify the supplier and will use all reasonable efforts to cause the supplier to promptly repair or replace the nonconforming Material in accordance with the supplier’s warranty. Provided the defective Material should have been detected by following the Testing Criteria (but such defective Material was not detected due to Plexus improperly executing the Testing Criteria prior to release to GenMark), any rework or service to repair a Product due to a Material defect within fifteen (15) months of GenMark’s purchase hereunder shall be performed by Plexus and GenMark shall pay \*\*\* of Plexus’ \*\*\* (not including the actual cost to replace the defective Materials, which will be fully borne by GenMark unless otherwise covered by such Material supplier’s warranty) to perform such rework and repair such Product to become a Warranty Compliant Product.  
  
5.2.2 Remedy. In the event any Product fails to conform to the warranties set forth in Section 5.2.1, Plexus shall, at Plexus’ election, repair or replace the Products \*\*\* . GenMark shall request a Return Materials Authorization (RMA) number from Plexus and return any Products not conforming to the warranties set forth in Section 5.2.1 bearing such RMA number. Plexus’ warranty for replaced or repaired Products shall be the longer of (1) the duration of the warranty remaining on the original Product returned under warranty, or (2) \*\*\* from the date of shipment of the replaced or repaired Product.  
  
5.2.3 Limitations. The warranties provided in Section 5.2 do not apply to (1) malfunctions, defects, or failures resulting from (a) misuse, (b) abuse, (c) accident, (d) neglect, (e) improper installation, operation, maintenance or repairs, (f) acts of God, (g) power failures or surges or (h) alterations, modifications, or repairs (“Repairs”) by any party other than Plexus, except for GenMark Field Service, provided GenMark Field Service does not make any Repairs outside the scope of Repairs the Parties agree in writing are acceptable for GenMark Field Service to perform; (2) any defect not made known by GenMark during the warranty period; and (3) Products shipped by Plexus and not tested according to the Testing Criteria at the direction of GenMark  
  
5.2.4 Disclaimer. THE REMEDIES PROVIDED IN THIS SECTION 5.2 CONSTITUTE GENMARK’S SOLE AND EXCLUSIVE REMEDIES AGAINST PLEXUS FOR BREACH OF WARRANTY CLAIMS. EXCEPT AS PROVIDED IN SECTIONS 5.1 AND 5.2, PLEXUS MAKES NO WARRANTIES OF ANY KIND WITH RESPECT TO THE PRODUCTS OR ITS SERVICES HEREUNDER, EXPRESS OR IMPLIED, INCLUDING ANY IMPLIED WARRANTIES RESPECTING NONINFRINGEMENT, OR MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE OR ANY IMPLIED WARRANTIES ARISING FROM A COURSE OF PERFORMANCE, A COURSE OF DEALING, OR TRADE USAGE.  
  
ARTICLE VI  
PROPRIETARY RIGHTS  
  
6.1 Definitions. “Plexus Background IP” means Intellectual Property Rights (i) existing as of the Effective Date, (ii) developed independently from this Agreement, or (iii) developed without the use of GenMark’s Confidential Information.  
  
6.2 Product Intellectual Property. Plexus hereby acknowledges and agrees that, except for Plexus Background IP, as between the parties, any and all Intellectual Property Rights necessary for or otherwise embodied in the Products and its design are and shall be and remain solely and exclusively owned by GenMark. The parties agree that the \*\*\* .  
  
6.3 Limited License to GenMark Intellectual Property Rights. During the term of this Agreement, GenMark grants Plexus a non-exclusive, non-transferable, limited right and license, without right to sublicense, to the GenMark Intellectual Property Rights solely to the extent necessary to manufacture and test Products for GenMark pursuant to the terms of this Agreement. No other rights, expressed or implied, to the GenMark Intellectual Property Rights are granted to Plexus hereunder.  
  
6.4 Manufacturing Instructions. Except as set forth in this Section 6.4, all right, title and interest to the Manufacturing Instructions shall be \*\*\* . Plexus hereby grants to GenMark a \*\*\* license to use the \*\*\* as necessary or helpful to manufacture or have manufactured the Products or any other products of GenMark or its Affiliates. In addition, the parties acknowledge and agree that Plexus will ensure that the Manufacturing Instructions are set forth in writing and will promptly, and in any event with \*\*\* , provide a complete set of the same to GenMark from time to time upon GenMark’s request. All rights and licenses granted to GenMark under or pursuant to this Section 6.4 are, and shall otherwise be deemed to be, for purposes of Paragraph 365(n) of the U.S. Bankruptcy Code, licenses of rights to “intellectual property” as defined under Paragraph 101(35A) of the U.S. Bankruptcy Code. The parties agree that GenMark, as licensee of such rights under this Agreement, shall retain and may fully exercise all of its rights and elections under the U.S. Bankruptcy Code.  
  
6.5 Inventions. GenMark shall solely and exclusively own the right to any and all Intellectual Property Rights that are conceived or reduced to practice by Plexus in its performance of this Agreement, except for Plexus Background IP  
  
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\*\*\* Portions of this page have been omitted pursuant to a request for Confidential Treatment and filed separately with the Commission.   
  
(“Inventions”). Plexus hereby irrevocably assigns and conveys to GenMark all right, title and interest worldwide in and to any and all Inventions as described in this Section 6.5 and agrees to execute any and all legal instruments and provide such other cooperation to GenMark as reasonably requested by GenMark, at GenMark’s expense, to effect, acknowledge or perfect such assignment and conveyance and maintain and prosecute such rights. Plexus represents and warrants that it has entered into or will enter into written agreements with all employees or other approved agents or representatives of Plexus performing activities hereunder necessary and appropriate to perfect GenMark’s ownership in all Inventions. Plexus retains no rights to use any Inventions and agrees not to challenge the validity of GenMark’s ownership of the Inventions. Plexus shall make a complete and prompt written disclosure to GenMark specifically detailing the features and concepts of any and all Inventions that are conceived or reduced to practice by Plexus and/or persons working under its direction in the manufacture of Products under this Agreement.  
  
6.6 Enforcement. GenMark shall have the sole power, authority and discretion to enforce and exploit the GenMark Intellectual Property Rights and Inventions against third parties. Plexus shall cooperate and assist GenMark as requested by GenMark in any legal action to enforce such rights. All costs of any such legal action, including any costs and expenses actually incurred by Plexus to support GenMark’s requests for assistance, shall be borne by GenMark, and any monetary relief granted as a result of such legal action shall accrue solely to GenMark. Plexus agrees to provide GenMark with prompt notice to the extent it has actual knowledge of, or reasonably suspects, any third party usage or infringement of the GenMark Intellectual Property Rights or Inventions.  
  
ARTICLE VII  
CONFIDENTIALITY  
  
7.1 Confidentiality Obligations. During the term of this Agreement and thereafter, each party: (a) shall treat as confidential all Confidential Information provided to the receiving party by the disclosing party, (b) shall not use such Confidential Information except as expressly permitted under the terms of this Agreement or otherwise authorized in writing by the disclosing party, (c) shall implement reasonable procedures to prohibit the disclosure, unauthorized duplication, misuse or removal of such Confidential Information, and (d) shall not disclose such Confidential Information to any third party unless it is necessary to fulfill one or more obligations expressly required by this Agreement, and provided that such third party agrees in writing to be bound by terms of confidentiality at least equivalent to those set forth in this Article VII. Without limiting the foregoing, each of the parties shall use at least the same procedures and degree of care to prevent the disclosure of Confidential Information as its uses to prevent the disclosure of its own confidential information of like importance, and shall in any event use no less than reasonable procedures and a reasonable degree of care. For purposes of this Article VII, “Confidential Information” means any and all non‑public and proprietary information that is designated as such and that is disclosed by either party to the other (including, without limitation, the GenMark Intellectual Property Rights and Plexus Background IP) in any form in connection with this Agreement and that, if orally disclosed, shall be identified in writing within thirty (30) days of such disclosure. A receiving party shall notify the disclosing party promptly upon discovery of any unauthorized use or disclosure of the disclosing party’s Confidential Information. Upon the expiration or earlier termination of this Agreement, each party shall return to the other party all tangible items regarding the Confidential Information of the other party and all copies thereof; provided, however, that a receiving party shall have the right to retain one (1) copy for its legal files for the sole purpose of determining its obligations hereunder.  
  
7.2 Permitted Disclosure. The obligations set forth in Section 7.1 shall not apply to any information to the extent it can be established by the receiving party that such information:  
  
(a)was generally known and available to the public at the time it was disclosed, or becomes generally known and available to the public through no fault of the receiving party;  
(b)was known to the receiving party at the time of disclosure as shown by written records in existence at the time of disclosure, or was independently developed by the receiving party or its Affiliates without the benefit of Confidential Information;  
(c)is disclosed with the prior written approval of the disclosing party;  
(d)becomes known to the receiving party from a third party without breach of this Agreement by the receiving party and in a manner that is otherwise not in violation of the disclosing party’s rights; or  
(e)is disclosed by the receiving party pursuant to the order or requirement of a court, administrative agency or other governmental body; provided, however, that the receiving party shall provide reasonable advance notice to enable the disclosing party, with the cooperation of the receiving party, to seek a protective order, confidential treatment order, or otherwise prevent or restrict such disclosure.  
  
7.3 Agreement and Terms Confidential. Unless otherwise agreed to in writing or as necessary to comply with a valid legal order of a court of law or agency of competent jurisdiction, both the existence and terms of this Agreement shall be deemed Confidential Information. If either party is required by the United States Securities and Exchange Commission (or  
  
  
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other similar Governmental Authority) to disclose this Agreement or any of its terms, such party shall consult with the other party, and give due consideration to such party’s comments regarding which terms the disclosing party may make the subject of a confidential treatment request. For the period commencing on the Effective Date and ending on the expiration or earlier termination hereof, without the prior express written consent of the other party, neither party shall originate any initial disclosure to any third party of the existence or terms of this Agreement (unless pursuant to an appropriate confidentiality agreement), or originate any initial publicity, news release or any other public announcement (written or oral) relating to this Agreement, the existence of an arrangement between the parties, or otherwise utilizing the other party’s trademarks or trade names.  
  
ARTICLE VIII  
INDEMNIFICATION AND INSURANCE  
  
8.1 Indemnification Obligations.  
  
8.1.1 Indemnification by Plexus. Plexus shall defend, indemnify and hold harmless GenMark and its Affiliates and their respective officers, directors, employees and agents (the “GenMark Indemnified Parties”) from and against any and all claims, suits or other actions made by a third party (collectively, “Claims”) and all related losses, expenses, damages, costs and liabilities (including reasonable attorneys’ fees) (collectively, “Losses”), arising out of or attributable to (a) the negligence or willful misconduct of Plexus, its Affiliates, or their respective officers, directors or employees in connection with the performance of their obligations under this Agreement resulting in bodily injury, death, or damage to tangible property; or (b) \*\*\* provided, however, that the foregoing obligation shall not apply to the extent such Losses are Losses for which GenMark must indemnify Plexus under Section 8.1.2.  
  
8.1.2 Indemnification by GenMark. GenMark shall defend, indemnify and hold harmless Plexus and its Affiliates and their respective officers, directors, employees and agents (the “Plexus Indemnified Parties”) from and against any and all Claims and all related Losses, arising out of or attributable to (a) Plexus’ manufacture of the aspect(s) of the Products in accordance with the Specifications which give rise to such Claim, (b) the negligence or willful misconduct of GenMark, its Affiliates, or their respective officers, directors or employees in connection with the performance of their obligations under this Agreement resulting in bodily injury, death, or damage to tangible property, (c) the marketing, distribution and sale of Products, or (d) infringement or misappropriation by the Products of any third-party Intellectual Property Right; provided, however, that the foregoing obligation shall not apply to the extent that such Losses are Losses for which Plexus must indemnify GenMark under Section 8.1.1.  
  
8.1.3 Indemnification Procedures. The parties shall promptly notify each other of any claims or suits with respect to which indemnification is sought hereunder. The party requesting indemnification shall permit the indemnifying party to assume the defense at the indemnifying party’s sole expense, of such claims or suits giving rise to indemnification hereunder. The indemnified party shall provide reasonable cooperation to the indemnifying party at the indemnifying party’s expense. The indemnified party may participate in any such proceedings with counsel of its own choosing at the indemnified party’s expense. No settlement or compromise shall be binding on a party to this Agreement without such party’s prior written consent, which consent shall not be unreasonably withheld.  
  
8.2 Limitation of Liability. neither party shall be liable TO THE OTHER for LOST PROFITS OR FOR ANY indirect, incidental, consequential, special, PUNITIVE or exemplary damages IN CONNECTION WITH THIS AGREEMENT OR THE TRANSACTIONS CONTEMPLATED BY THIS AGREEMENT, however caused, under any theory of liability INCLUDING CONTRACT, TORT (INCLUDING NEGLIGENCE) OR OTHERWISE, AND NOTWITHSTANDING THAT SUCH DAMAGES MAY HAVE BEEN IN THE REASONABLE CONTEMPLATION OF THE PARTIES. the limitations of liability set forth in this section 8.2 shall not apply to BREACH OF CONFIDENTIALITY OBLIGATIONS OR VIOLATIONS OF THE OTHER PARTY’S INTELLECTUAL PROPERTY RIGHTS HEREUNDER, OR TO A PARTY’S GROSS NEGLIGENCE OR WILLFUL MISCONDUCT.  
  
8.3 Insurance. Each party shall, at its own expense, procure and maintain insurance with a financially sound insurance company having an A.M. Best Rating of AX or better in the areas of worker’s compensation; employer’s liability for bodily injury suffered through accident or disease; commercial general liability; and product liability with limits of no less than \*\*\* per occurrence for bodily injury and \*\*\* per occurrence for property damage and with limits for comprehensive general liability and product liability that are consistent with normal business practices of prudent companies similarly situated at all times during which any Product is being commercially distributed or sold by GenMark. Upon written request, a party shall furnish the other party with a certificate of insurance evidencing the coverage required hereunder and shall provide thirty (30) days’ prior written notice to the other party in the event of cancellation or material adverse change in such coverage. It is understood that  
  
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\*\*\* Portions of this page have been omitted pursuant to a request for Confidential Treatment and filed separately with the Commission.   
  
such insurance shall not be construed to create a limit of either party’s liability with respect to its indemnification obligations under Section 8.1.  
  
ARTICLE IX  
TERM AND TERMINATION  
  
9.1 Term and Termination. The term of this Agreement shall commence on the Effective Date and, unless terminated earlier pursuant to this Section 9.1, shall continue until the fifth (5th) anniversary of the Effective Date, after which it shall renew automatically for successive two (2) year periods unless either party provides the other party with written notice at least twelve (12) months in advance of a scheduled renewal date of its intent not to renew this Agreement.  
  
9.1.1 Termination for Insolvency. Either party may terminate this Agreement upon thirty (30) days prior written notice to the other party if the other party has experienced an Insolvency Event.  
  
9.1.2 Termination for Breach. Either party may terminate this Agreement after the material breach of this Agreement by the other party, unless the breaching party has cured a non-payment breach within \*\*\* days after written notice thereof from the non-breaching party or a payment breach within \*\*\* days after written notice thereof from the non-breaching party.  
  
9.1.3 Termination for Convenience. Either party shall have the right to terminate this Agreement for its convenience, with or without cause, at any time after \*\*\* of the Effective Date upon \*\*\* written notice to the other party. In the event Plexus exercises its right to terminate for convenience pursuant to this Section 9.1.3 during the initial five (5) years of the term, Plexus shall (a) cooperate with GenMark in effecting the disclosure and transfer of all \*\*\* , Product-specific know-how and Product-specific quality control procedures as are necessary or useful to commence and continue the uninterrupted manufacture and supply of Products and Spare Parts, (b) continue the uninterrupted supply of Products and Spare Parts pursuant to the terms of this Agreement until GenMark’s alternative supply source has been validated but in no event longer than \*\*\* after the expiration of the \*\*\* notice period, (c) cover the reasonable costs and expenses associated with shipping test fixtures and Materials to GenMark or its designee, and (d) at GenMark’s request, Plexus shall coordinate a last-time-buy of Materials and/or Spare Parts.  
  
9.2 Effect of Termination.  
  
9.2.1 Survival. Notwithstanding anything contained in this Agreement to the contrary, termination of this Agreement shall not relieve the parties of their respective obligations or liability to the other accrued hereunder prior to the effective date of termination. The following provisions shall survive the termination or expiration of this Agreement: Section 2.2 (Spare Parts); Section 4.3 (Unconditional Right to Remove GenMark Equipment); Section 5.2 (Plexus’ Manufacturing Warranties); Article VI (Proprietary Rights); Article VII (Confidentiality); Section 8.1 (Indemnification Obligations); Section 8.2 (Limitation of Liability); Section 9.2 (Effect of Termination); Section 9.3 (Return of Information and Cooperation); Article X (Arbitration); Section 11.1 (Interpretation); Section 11.3 (Notices); Section 11.8 (Governing Law); Section 11.9 (Legal Counsel); Section 11.11 (Severability); Section 11.12 (Headings); and any other provisions of this Agreement which by their nature or context are intended or required to survive the expiration or termination of this Agreement.  
  
9.2.2 Non-Exclusive Remedy. Termination of this Agreement shall be in addition to, and shall not prejudice, the parties’ remedies at law or in equity, including, without limitation, the parties’ ability to receive legal damages and/or equitable relief with respect to any breach of this Agreement, regardless of whether or not such breach was the reason for the termination.  
  
9.2.3 Return of Information and Cooperation. In the event of termination of this Agreement, Plexus shall promptly return and provide to GenMark all Program Material and Confidential Information of GenMark. Upon any termination (including expiration) of this Agreement, the parties will cooperate to minimize disruption to GenMark’s customers and to provide for the continued manufacture of Products if so requested by GenMark. Except in the event of termination arising from GenMark’s breach of this Agreement, Plexus will fill existing orders that Plexus has received and accepted.  
  
9.2.4 Inventory. Upon termination of this Agreement for any reason, all outstanding purchase orders may, at GenMark’s written election, be canceled. Otherwise, Plexus will perform under such purchase orders and the provisions of this Agreement will survive termination and apply to such performance. If this Agreement is terminated by GenMark pursuant to Section 9.1.3 or by Plexus pursuant to Section 9.1.2, GenMark agrees to pay Plexus for (1) any finished goods Products; (2) any work-in-progress Products; and (3) provided that Plexus procured the Materials in accordance with this Agreement, any Materials, at the cost set forth on the Xxxx of Materials, plus an amount equal to the Applicable Materials Overhead Percentage multiplied by such cost, on hand, on order or for which Plexus is obligated to purchase as of the date of termination, subject to Plexus’ obligation  
  
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\*\*\* Portions of this page have been omitted pursuant to a request for Confidential Treatment and filed separately with the Commission.   
  
to mitigate and limit all such amounts in accordance with Section 2.5.3.4. In the event this Agreement is terminated by GenMark pursuant to Section 9.1.2, GenMark agrees to pay Plexus for (1) any finished goods Products; and (2) provided that Plexus procured the Materials in accordance with this Agreement, any Materials, at cost set forth on the Xxxx of Materials, on hand, or on order or for which Plexus is obligated to purchase as of the date of termination, subject to Plexus’ obligation to mitigate and limit all such amounts in accordance with Section 2.5.3.4.  
  
ARTICLE X  
ARBITRATION  
  
10.1 Disputes. Except as otherwise expressly provided in this Agreement, any controversy, claim or legal proceeding arising out of or relating to this Agreement, or the breach, termination or invalidity thereof (“Dispute”) shall be first referred to GenMark’s Chief Executive Officer and Plexus’ Chief Customer Officer for resolution, prior to proceeding under the other provisions of this Article X. A Dispute shall be referred to such executives upon one party providing the other party with notice that such Dispute exists, and such executives (or their designees) shall attempt to resolve such Dispute through good faith discussions. In the event that such Dispute is not resolved within thirty (30) days of such other party’s receipt of such notice, subject to Section 10.3, either party may initiate the Dispute resolution provisions in Section 10.2. The parties agree that any discussions between such executives (or their designees) regarding such Dispute do not constitute settlement discussions, unless the parties agree otherwise in writing.  
  
10.2 Arbitration. Subject to Sections 10.1 and 10.3, the parties agree to resolve any Dispute exclusively through binding arbitration conducted under the auspices of the American Arbitration Association (the “AAA”) pursuant to AAA’s Commercial Arbitration Rules presently in effect. The parties shall appoint an arbitrator with at least ten (10) years of experience as an attorney and experience in the medical diagnostics industry so as to better understand the legal, business and scientific issues addressed in the arbitration. Any arbitration hereunder shall be brought in San Diego, California. Unless agreed otherwise by the parties, the parties shall have thirty (30) days from the appointment of the arbitrator to present and/or submit their positions to the arbitrator, and the parties shall have a hearing before the arbitrator within ten (10) business days of such submission. Each party agrees to use reasonable efforts to make all of its current employees available, if reasonably needed, and agrees that the arbitrator may deem any party as “necessary.” The arbitrator shall hear evidence by each party and resolve each of the issues identified by the parties. The arbitrator shall be instructed and required to render a written, binding, non-appealable resolution and award on each issue which clearly states the basis upon which such resolution and award is made. The written resolution and award shall be delivered to the parties as expeditiously as possible, but in no event more than thirty (30) days after conclusion of the hearing, unless otherwise agreed to by the parties. The parties shall use all reasonable efforts to keep arbitration costs to a minimum. Each party must bear its own attorneys’ fees and associated costs and expenses. Each party agrees that, notwithstanding any provision of applicable law or of this Agreement, it will not request, and the arbitrators shall have no authority to award, punitive or exemplary damages against any party.  
  
10.3 Subject Matter Exclusions. Notwithstanding the foregoing, the provisions of Sections 10.1 and 10.2 shall not apply to any Dispute relating to: (a) the validity, infringement, enforceability or claim interpretation relating to a party’s patents, trademarks or copyrights, which, for patents that are issued in the United States, shall be subject to actions before the United States Patent and Trademark Office and/or submitted exclusively to the federal court located in the jurisdiction of the district where any of the defendants reside; or (b) any antitrust, antimonopoly or competition law or regulation, whether or not statutory.  
  
10.4 Equitable Relief. Nothing in this Agreement shall be deemed as preventing the parties from seeking injunctive relief (or other provisional remedy) from any court having jurisdiction over the parties and the subject matter of the dispute as necessary to protect either party’s interests.  
  
ARTICLE XI  
MISCELLANEOUS PROVISIONS  
  
11.1 Interpretation. In this Agreement, unless a clear contrary intention appears:  
  
(a)the singular number includes the plural number and vice versa;  
  
(b)reference to any person or entity includes such person’s or entity’s successors and assigns;  
  
(c)reference to any law, rule, regulation, order, decree, requirement, policy, guideline, directive or interpretation means, unless specified otherwise, as amended, modified, codified, replaced or re-enacted, in whole or in part, and in effect on the determination date, including rules, regulations and applicable guidance promulgated thereunder;  
  
  
  
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(d) “hereunder”, “hereof”, “hereto”, “herein” and words of similar import shall be deemed references to this Agreement as a whole and not to any particular Article, Section or other provision hereof; and “including” (and with correlative meaning “include”) means including without limiting the generality of any description preceding such term.  
  
11.2 Independent Contractors. It is expressly agreed that GenMark and Plexus shall be independent contractors and that the relationship between the parties shall not constitute a partnership, joint venture or agency. Neither GenMark nor Plexus shall have the authority to make any statements, representations or commitments of any kind, or to take any action, which shall be binding on the other, without the prior written consent of the party to do so.  
  
11.3 Notices. Any consent, notice or report required or permitted to be given or made under this Agreement by one party to the other shall be in writing, addressed to such other party at its address indicated below, or to such other address as the addressee shall have last furnished in writing to the addressor, and shall be effective: (a) if sent by registered or certified mail in the United States return receipt requested, upon receipt; (b) if sent by nationally recognized overnight air courier (such as DHL or Federal Express), two (2) business days after mailing; and (c) if otherwise actually personally delivered, when delivered.  
  
If to GenMark: GenMark Diagnostics, Inc.  
0000 Xx Xxxxx Xxxxx  
Xxxxxxxx, Xxxxxxxxxx 00000  
Attention: Chief Executive Officer  
Copy to: General Counsel  
  
If to Plexus: Plexus Corp.  
Xxx Xxxxxx Xxx  
Xxxxxx, Xxxxxxxxx 00000  
Attention: Executive VP & Chief Customer Officer  
Copy to: General Counsel  
  
11.4 Noninterference. Plexus represents and warrants that no provision of this Agreement is in any way in conflict with or impairs the performance of any present contractual obligation to any third party and neither Plexus nor any persons employed by Plexus or who assist Plexus in this project will assume any obligation or restriction which will conflict with or prevent them from performing any of the services contemplated by this Agreement.  
  
11.5 Assignments, Succession and Waivers. Neither this Agreement nor any part thereof shall be assignable by the other party without the express written consent of the other party, and any attempted assignment shall be null and void, provided, however, that either party may assign this Agreement to an Affiliate of such party or to a Person that succeeds to all or substantially all of that party’s business or assets whether by sale, merger, operation of law or otherwise. This Agreement shall be binding upon and shall inure to the benefit of the parties, their successors and permitted assignees. No express waiver or any prior breach of this Agreement shall constitute a waiver of any subsequent breach hereof and no waiver shall be implied.  
  
11.6 Force Majeure. If the performance of this Agreement or any obligations hereunder is prevented, restricted or interfered with by reason of fire or other casualty or accident, strikes or labor disputes, war or other violence, any law, order, proclamation, ordinance, demand or requirement of any government agency, or any other act or condition beyond the control of the parties hereto (“Force Majeure”), the party so affected, upon giving prompt notice to the other party shall be excused from such performance during such prevention, restriction or interference. If the Force Majeure continues for more than \*\*\* , then the other party may by written notice to the affected party terminate this Agreement.  
  
11.7 Integration. This Agreement (together with the Exhibits, Schedules and Appendices hereto), expresses the entire understanding between GenMark and Plexus with respect to the subject matter hereof and merges all prior oral discussions or written correspondence between them, except that the rights and obligations contained in any confidentiality agreement(s) executed by the parties prior to the Effective Date shall not be deemed waived, amended, superseded or otherwise affected hereby. No notification, extension, amendment or waiver of this Agreement or any provision hereof shall be binding unless agreed to in writing by the parties.  
  
11.8 Governing Law. This Agreement shall be governed by and construed in accordance with the laws of the State of New York.  
  
11.9 Legal Counsel. Each party is a sophisticated business entity which has involved legal counsel of its own choosing in drafting, negotiating and concluding this Agreement and any presumption in statutory or common law against the drafter of  
  
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\*\*\* Portions of this page have been omitted pursuant to a request for Confidential Treatment and filed separately with the Commission.   
  
any particular provision herein, or against the drafter of this Agreement as a whole, shall be of no effect whatsoever and each party shall refrain from asserting or relying upon any such presumption.  
  
11.10 Affiliate Performance. Either party may perform all or part of its obligations hereunder, and may exercise any of its rights hereunder, by or through any Affiliate of the party; provided that nothing herein shall relieve such party of its obligations hereunder unless expressly authorized by the other party in writing.  
  
11.11 Severability. If any provision of this Agreement is held unenforceable or in conflict with applicable law, it is the intention of the parties that the validity and enforceability of the remaining provisions hereof shall not be affected thereby.  
  
11.12 Headings. All article and section captions or titles are intended only for reference purposes and are without contractual significance or effect.  
  
11.13 Counterparts. This Agreement may be executed in one or more counterparts, each of which will be deemed to be an original, but all of which together will constitute one and the same instrument; however, this Agreement shall have no force or effect until executed by both parties.  
  
  
[Remainder of Page Left Intentionally Blank]  
  
   
   
  
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IN WITNESS WHEREOF, the parties hereto have executed this Agreement as of the Effective Date:  
  
  
CLINICAL MICRO SENSORS, INC. Plexus Corp.  
D.B.A GenMark DIAGNOSTICS, INC.   
  
  
  
  
By: /s/ Xxxx Xxxxxxxxx By: /s/ Xxxxxx X. Xxxxxx  
Name: Xxxx Xxxxxxxxx Name: Xxxxxx X. Xxxxx  
Title: Chief Executive Officer Title: Executive VP & Chief Customer Officer  
   
  
  
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Exhibit A  
Quality Agreement  
  
Quality Assurance Agreement  
Between Plexus and GenMark  
  
Contents  
  
Note: This quality assurance agreement was written so that Article I contains general information to the supplier. Article III states requirements applicable to every supplier regardless of the product purchased by GENMARK. Then each of the following articles contains additional requirements depending on the product purchased.  
  
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A. Supplier’s executive management responsibility.  
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A. Calibration requirements.  
B. Calibration procedures.  
  
5. GENMARK right to inspect (Audit)  
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B. GENMARK Audits.  
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D. Storage.  
  
2. Production and process controls  
A. Engineering drawings.  
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Article I. Purpose (Informative)  
  
1. Introduction  
  
Medical device manufacturers, such as (GENMARK), are obligated to follow many regulations and standards relating to product quality which may include, but are not limited to, the following:  
  
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TITLE 21 Code of Federal Regulations Part 820 - Quality System Regulation  
  
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Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on in vitro diagnostic medical devices (IVD Directive)  
  
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ISO 13485:2003 Medical Device Quality Management System  
  
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ISO 9001:2008 Quality Management Systems  
  
In general these regulations prescribe what medical device manufacturers must do during design, manufacturing, and post-manufacturing. While they do not directly apply to suppliers of medical device manufacturers, it is the responsibility of GENMARK and other medical device manufacturers to assure that only product conforming to specified requirements is used.  
  
These regulations explicitly require that the finished device manufacturer assess the capability of suppliers to provide quality products and services. Because of the complexity of the many parts used in GENMARK devices, their adequacy cannot always be assured through inspection and testing by GENMARK. Quality must be assured through the application of proper quality systems.  
  
As medical device and diagnostics products become more complex and as demand increases, the chance of errors and inconsistencies in manufacturing escalate. Only by implementing systematic processes and quality controls during the product life cycle (e.g.: design, manufacture, installation and service) can manufacturers like GENMARK eliminate variability that can lead to regulatory actions, devastating product recalls, and lost market share. Therefore, GENMARK expects that all of our suppliers will collaborate with GENMARK and support our effort in meeting our obligations for medical device manufacturers.  
  
  
2. Quality system requirements in general  
  
GENMARK requires that our suppliers establish and maintain a quality management system that is appropriate for the specific product being manufactured or the service performed that ensures the users of GENMARK products receive and operate safe, effective, and reliable medical equipment.  
  
GENMARK expects its suppliers to have processes that ensure that they meet the quality system requirements specified herein. It also recognized that some suppliers are small businesses while others are large corporations. Exactly how a supplier establishes and maintains their quality system to meet GENMARK’ requirements is dependent upon the supplier’s operation and is appropriate for the business size of the supplier provided that quality, reliability, maintainability and regulatory requirements are maintained at the highest level.  
  
In this document, a requirement means a specification or characteristic with which a product, process, service, or other activity being performed for GENMARK must conform. Product means component, material, substance, piece, part, software, firmware, assembly, and finished device to be used in or with a finished medical device, or a service performed to design, develop, install, repair, or maintain a finished medical device and its accessories.  
  
These requirements have been established in order to assist GENMARK in meeting our obligations for safety, quality, and reliability.  
  
3. Notes regarding regulations and standards  
  
A. FDA regulations. Manufacturers that are registered with FDA as a device manufacturer or as a contractor which manufactures and supplies GENMARK with accessories that function with GENMARK equipment are expected to follow all applicable FDA regulations in addition to the requirements herein. Non-medical device manufacturers that supply accessories that function with GENMARK equipment or other products are expected to follow all of the requirements herein, as appropriate.  
  
  
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B. IVD Directive (Directive 98/79/EC). All medical devices sold within the EU member states must meet certain essential safety and administrative requirements, defined in the IVD Directive, before they can be marked with the applicable CE xxxx by the manufacturer.  
  
C. ISO standards. GENMARK does not mandate that all of it suppliers be certified to an ISO standard. However, if an ISO certification does exist, the supplier shall meet the standard’s requirements. The requirements given herein will be used by GENMARK when evaluating the effectiveness of a supplier’s quality management system (QMS).  
  
  
Article II. Scope  
  
This quality assurance agreement (QAA) applies to the manufacture and delivery of products to GENMARK by the supplier. When this annex is blank or does not reference the Scope of Work, then this QAA applies to all products procured by GENMARK from the supplier.  
  
1. Applicable Products  
  
This Quality Assurance Agreement (QAA) applies to the following product(s) delivered by the supplier to GENMARK. If nothing follows, then the QAA applies to all products ordered by GENMARK.  
  
2. Additional Requirements Not Stated in the QAA  
  
The following special requirements (barcoding, product labeling, testing, inspection, packaging, documentation, etc.) are in addition to the QAA. If nothing follows, then there are no additional requirements not stated in the QAA.  
  
3. Exclusions to the QAA  
  
The following are exclusions to the QAA as agreed to between GENMARK and the supplier. If nothing follows, then there are no exclusions to the QAA. This QAA is specific to the manufacturing of the  
  
Article III. Quality Assurance Requirements Applicable to All Suppliers  
  
1. Quality system  
  
A. Establishment. It is expected that the seller has established and is maintaining a quality management system that is commensurate with the product being provided to GENMARK or in support of GENMARK’ business. It is further expected that the supplier’s quality system has been established to ensure that all GENMARK requirements are understood and are being met.  
  
For the exchange of quality-relevant information between the parties via e-mail, appropriate software for electronic signature and encryption has to be used, where appropriate.  
  
B. GENMARK requirements. The supplier is required to ensure that it has received and understands all requirements received from GENMARK in writing.  
  
C. Deviations. The supplier shall receive written authorization from a representative of GENMARK prior to making any changes to any GENMARK requirement, including the requirements herein. Failure to comply with this GENMARK requirement could have a serious impact resulting in the GENMARK medical device becoming adulterated within the meaning of U.S. Federal Regulations.  
  
D. Process control plan. The supplier shall: (a) define and document (i.e. in a process map, in a flow diagram, or etc.) the processes it uses, from order receipt to order fulfillment, necessary to provide the product for GENMARK; (b) verify that these processes are effective in producing the desirable product for GENMARK, (c) establish the methods to appropriately monitor, measure and control these processes to ensure that product requirements are consistently meeting GENMARK’ requirements; and (d) provide, when appropriate, for a means to analyze process trends and take prompt action to correct any unfavorable trend.  
  
E. Quality system procedures. The supplier shall have documented procedures and instructions to effectively implement the established quality system and support the process plan.  
  
  
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F. GENMARK owned property. The supplier is responsible for identifying, controlling, maintaining, storing, and, where appropriate, calibrating GENMARK owned property. The supplier is required to timely notify GENMARK in the event that any GENMARK property is lost or damaged, or that its continued use could result in nonconforming product.  
  
This includes, but not limited to, meters, gages, tools, fixtures, instruction manuals, installation aids, and software provided by GENMARK to the supplier to provide product to GENMARK.  
  
The use of such property is limited to making/providing product for GENMARK and may not be used by the supplier for any other purpose without written approval from an agent of GENMARK.  
  
GENMARK will reimburse Plexus for expenses associated with maintaining and as appropriate calibrating GENMARK owned property in accordance with section 4.1 of the Agreement.  
  
GENMARK will provide Plexus with sufficient information to verify, calibrate, operate, test and maintain any GENMARK supplied property.  
  
G. Complaints from GENMARK customers. While it is reasonable to expect that the supplier will have some interaction with a customer of GENMARK, the supplier is required to have a written procedure for forwarding to a representative of GENMARK, without undue delay, any written, electronic, or oral communication from a customer of GENMARK that alleges deficiencies related to the identity, quality, durability, reliability, safety, effectiveness, or performance of any of GENMARK equipment.  
  
GENMARK is responsible for all complaint handling in accordance with section 3.11 of the Agreement.  
  
H. Complaints from GENMARK. The supplier is to establish a process for receiving a complaint from GENMARK alleging nonconformity of the supplier’s product and providing timely feedback to GENMARK reporting on the corrective action it has taken or rationale for not taking corrective action.  
  
The supplier shall have a written procedure describing the corrective action process. The procedure is to include:  
1.  
the department or staff responsible for receiving, reviewing, evaluating and coordinating complaints from GENMARK  
2.  
documenting oral complaints upon receipt,  
3.  
processing complaints in a timely and uniform manner,  
4.  
the investigation process to determine the root cause of the problem,  
5.  
evaluating the need for action to ensure that the problem does not recur,  
6.  
determining and implementing the action needed to provide a solution to the problem,  
7.  
action on product already delivered and/or other sites or systems that could be affected by the nonconformity,  
8.  
verification of activities to show that the actions taken were effective,  
9.  
management review and approval of the action taken, and  
10.  
maintaining records of corrective actions. Corrective action records are to be made available to GENMARK upon request.  
  
I. Management representative. The executive management is to appoint a member of management who, irrespective of other responsibilities, is the supplier’s management representative for quality. This manager shall have the overall responsibility and authority to ensure that the quality system is effectively established and being maintained. This individual must be available to be contacted by a representative of GENMARK whenever issues of product quality arise.  
  
J. Personnel training. The supplier is responsible for maintaining sufficient personnel with the necessary education, background, training, and experience to assure that the established quality system and process plan are correctly implemented. Personnel are to be adequately trained and qualified to perform their assigned responsibilities according to an established training plan. Untrained, unqualified personnel are only to perform work while under the supervision of qualified personnel so they do not damage or otherwise cause harm to the product. The supplier shall also ensure that its personnel receive up-to-date retraining, as appropriate, whenever processes, methods, technology or other changes reasonably suggest that retraining is necessary. Records of all training must be maintained by the supplier to document that personnel have been trained in accordance with the requirements of the established training plan and these records are to be made available to GENMARK upon request.  
1.  
Blood borne pathogens. Where it is reasonable to expect that personnel might come into contact with used medical devices of any kind, the supplier is responsible for training their personnel in the OSHA regulations for blood borne pathogens. This includes returning component parts for failure investigation or complaint processing. (See xxx.xxxx.xxx for further information)  
  
  
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2.  
HIPAA. Where it is reasonable to expect that employees or agents of the supplier might have access to patient records, either by need or accidentally, the supplier must comply with the Health Insurance Portability and Accountability Act (1996) to maintain the confidentiality and privacy of any such patient information. (See xxx.xxx.xxx/xxx/xxxxx for more information.)  
3.  
ESD. Where it is reasonable to expect that electro-static discharge (ESD) could affect the requirements of product, including product being returned to GENMARK for failure investigation, supplier shall ensure that their personnel are trained in ESD controls, including handling and packaging.  
  
K. Changes to quality system or product. The supplier’s executive management is responsible for notifying GENMARK of any change (prior to implementation) to the product, including the process plan, when the change could affect product quality, so that GENMARK may determine whether the change affects the quality, reliability, safety, or efficacy of the finished medical device. The supplier shall have a documented process identifying how it will inform GENMARK of any such quality system and product changes.  
  
2. Control of documents and records  
  
A. Control of documents. Documents required by the quality system are to be controlled according to a written procedure. These include, for example, procedures, drawings, instruction manuals, service manuals, test methods, inspection instructions, specifications, and product literature.  
  
B. Reserved.  
  
C. Change control. Changes (revisions) to documents are to be reviewed and approved by personnel who are as capable as the original reviewers and approvers.  
1.  
Changes to documents are to be timely communicated by the supplier to appropriate personnel.  
2.  
The supplier must establish and maintain a system to receive GENMARK document revisions and implement these revisions in a timely manner.  
3.  
Suppliers are not permitted to accept and act on verbal change requests from GENMARK and GENMARK is not permitted to provide verbal change requests to Supplier.  
  
D. Availability of documents. Documents are to be readily available to the supplier’s personnel at their intended point-of-use.  
  
E. Control of records. Records are a special type of document. Records are typically completed forms, checklists or other evidence that demonstrate that requirements have been met and the effective operation of the quality system. Records are to remain legible. Records are to be controlled according to a written procedure which shall include the controls needed for the identification, storage, protection and disposal. Records are to be retained for at a minimum of 10 years. A copy of a record(s) is to be made available to GENMARK within 2 business days of request. Additionally, the provisions for archiving device specific documents shall survive the termination of the QAA.  
  
Following expiration of the retention periods, the supplier shall offer to transfer device specific records to GENMARK free of charge.  
  
F. Electronic documents and records. Where electronic systems are used for the control of documents, the system must be validated to ensure that only approved documents are made available at the point-of-use, write protection is provided, and approval forgery is prevented. Where records are stored electronically, the system shall have appropriate controls to ensure that only true copies of records are stored and controls in place to preclude unauthorized changes and loss.  
  
3. Purchasing controls  
  
A. Approval of subtier suppliers. The supplier is to evaluate their own suppliers to the extent necessary to ensure quality products are being provided. Approvals of subtier suppliers are to be based on this evaluation. The supplier shall establish and maintain an approved supplier list. In the event that GENMARK has provided an approved supplier list to the supplier, any deviations must be approved by GENMARK prior to purchase of any product. Controls are to be in place to assure that purchases are only made from approved suppliers.  
  
B. Specific GENMARK requirements. When the GENMARK engineering drawings or other GENMARK document specifies the subtier supplier to be used, the supplier is to ensure that these requirements are followed. GENMARK specified subtier suppliers are to be added to the supplier’s approved supplier list. No substitutions or alternates to a specified subtier supplier are to be made without written consent from an authorized representative of GENMARK.  
  
  
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C. Quality control of 3rd party products  
The supplier is responsible for assessing the quality system and for the quality of product received from all third-party suppliers it uses.  
  
If the supplier receives production or test equipment, software, services, materials or other supplies from third parties for the manufacture or quality assurance of its products, the supplier shall ensure that these are in compliance with its quality management system, whether it be by contract with these parties or through carrying out such tests itself as are necessary to assure compliance with its quality management system.  
  
D. Purchase information. Purchase orders shall include adequate information, including quality requirements, so as to be precise and unambiguous as to what is being purchased.  
  
E. Traceability. GENMARK shall define any “critical” components requiring component level traceability. GENMARK shall also select the appropriate component level or device level traceability grade, in order to meet any applicable FDA requirements or regulations. Plexus is responsible for implementing the defined manufacturing-level traceability requirements and for ensuring that the appropriate manufacturing-level traceability records and associated records are retained for the duration of this Agreement.  
  
4. Calibration of inspection, measurement and test equipment  
  
A. Calibration requirements. Any equipment used to establish product specifications during design and development, used to determine process parameters, or used to judge the acceptability of a product specification shall be maintained under a calibration program.  
  
B. Calibration procedures. Procedures shall be established and maintained to ensure that inspection, measuring, and test equipment (IM&TE) used to determine the acceptance or rejection of process or product requirements during design, production, installation or service are calibrated, inspected, checked and maintained in accordance with the manufacturer’s recommendations. Calibration procedures shall include specific directions and limits for accuracy and precision. Calibration standards used for IM&TE must be in conformity to national or international standards.  
  
C. Suitability of equipment. Suppliers shall ensure that all IM&TE, including mechanical, automatic, or electronic inspection and test equipment, are suitable for their intended use and capable of producing valid results. Controls shall be in place to ensure that IM&TE maintain their suitability while in-use, in transit, or in storage.  
  
D. Calibration labeling. A label is to be affixed on or, if appropriate, near the IM&TE. This is to inform the user of the IM&TE that the IM&TE is under the calibration program. The label is to include: (a) date IM&TE was calibrated, (b) who performed the calibration, and (c) the due date of the next calibration.  
  
E. Calibration records. Supplier is responsible for maintaining records to provide objective evidence that IM&TE are being maintained and calibrated. These records shall be made available to GENMARK upon request.  
  
F. Notification to GENMARK. The supplier shall notify GENMARK without undue delay when the supplier becomes aware of the use of any inappropriate or out-of-calibration inspection measurement and test equipment so that GENMARK can evaluate the effect of its use and any necessary corrective or other action, up to and including reworking at the supplier’s expense.  
  
G. Use of calibration lab. When the supplier uses the services of an outside calibration service, it is the responsibility of the supplier to ensure that the service provider meets any and all requirements for the service provided.  
  
5. GENMARK right to inspect (Audit)  
  
A. Supplier’s executive management responsibility. To ensure the effectiveness of the supplier’s quality system to deliver conforming product, GENMARK may require representatives of GENMARK to perform quality system audits at the supplier’s facility. The supplier’s executive management shall support such audits and ensure that prompt corrective actions are taken to address any discrepancies found.  
  
B. GENMARK Audits. The supplier shall at reasonable intervals allow GENMARK to check the compliance with this quality assurance agreement. The supplier shall therefore, after prior agreement of the parties on the date of such an inspection,  
  
  
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grant GENMARK reasonable access to its business premises and shall make available a duly qualified member of its staff for the duration of the inspection visit. GENMARK may be denied access to and inspection of classified manufacturing methods and other industrial secrets.  
  
This described right of GENMARK includes the right to inspect the existing documentation and to participate in quality checks carried out by the supplier. The checks may be carried out by way of quality audits (e.g. audits involving the systems, products or processes) and via inspections.  
  
C. Third party audit. An audit or regulatory inspection may also be required from time to time. This may involve the authority having jurisdiction over GENMARK according to the European IVDD 93/42/EEC or any other regulatory authority (e.g., US Food and Drug Administration) or authorized organization or by third parties commissioned by GENMARK.  
  
6. Corrective and preventive action (CAPA)  
  
A. Basic CAPA requirements. The suppliers shall establish procedures for implementing corrective and preventive action. The procedures shall include requirements for:  
1.  
Analyzing processes, work operations, concessions, quality audit reports, quality records, service records, complaints, returned product, and other sources of quality data to identify existing and potential causes of nonconforming product, or other quality problems. Appropriate statistical methodology shall be employed, where necessary, to detect recurring quality problems;  
2.  
Investigating the cause of nonconformities relating to product, processes, and the quality system;  
3.  
Identifying the action(s) needed to correct and prevent recurrence of nonconforming product and other quality problems;  
4.  
Verifying or validating the corrective and preventive action to ensure that such action is effective and does not adversely affect the finished device;  
5.  
Implementing and recording changes in methods and procedures needed to correct and prevent identified quality problems;  
6.  
Ensuring that information related to quality problems or nonconforming product is disseminated to those directly responsible for assuring the quality of such product or the prevention of such problems;  
7.  
Submitting relevant information on identified quality problems, as well as corrective and preventive actions, for management review; and  
8.  
Ensuring that all activities required under this section, and their results, are properly documented.  
  
Annex I. Specific Requirements for Manufacturing  
  
NOTE: This section applies to suppliers producing, assembling, fabricating or processing product for GENMARK.  
  
1. Receiving, receiving inspection, and storage  
  
A. Authorized receipts. The receiving function shall ensure that only deliveries from 3rd party suppliers that are listed on the supplier’s approved supplier list are accepted and processed. Articles leaving the receiving function must be clearly labeled or otherwise identified so as to preclude mix-ups and unintentional use. Nonconforming articles are to be clearly labeled and separated from all other articles.  
  
B. Direct to stock receipts. When received articles bypass receiving inspection and go directly to storage or to their point-of-use, controls must be in place to avoid mistakes and the unintentional acceptance of articles.  
1.  
The acceptance of these articles must have some form of prior documented approval, including the rationale, to bypass receiving inspection.  
2.  
The receiving function shall record the acceptance of the articles after verifying they meet predetermined requirements.  
  
C. Receiving inspection. Receiving inspection activities shall be established and maintained in a written procedure. These activities are to confirm or to otherwise verify that incoming articles conform to specified requirements. When other than 100% inspection is performed, the sample size is to be determined based on the risk of accepting the lot when it should have been rejected. Only published sampling plans may be used (i.e., ANSI/ASQC Z-1.4). Receiving inspections are to be recorded and include (1) the inspection/tests performed, (2) date inspection/tests were performed, (3) results -acceptance or rejection, (4) the signature of the inspector, and (5) where appropriate, the test equipment used. Articles leaving the receiving function must be clearly labeled or otherwise identified so as to preclude mix ups and unintentional use. Nonconforming articles are to be clearly labeled and separated from all other articles.  
  
D. Storage. Stockrooms, where materials and parts are stored for later use in production, are to be kept orderly and well maintained. Only items that have been accepted for use are to be stored in the stockroom. All bins, cartons, or other containers holding the items in storage are to be labeled with the item’s part number and be of such design as to preclude mix ups.  
  
  
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Controls are to be in place to prevent damage and deterioration while items are in storage. Controls for temperature sensitive and limited shelf life materials must be considered.  
  
2. Production and process controls  
  
A. Engineering drawings. In cases where the supplier receives GENMARK engineering drawings and then imports them into the supplier’s engineering drawing format for internal use, confidentiality of both sets of drawings is to be maintained. Both sets of drawings are to remain the property of GENMARK.  
  
B. Inspections and tests. Whether required by GENMARK or not, the supplier is responsible for conducting all appropriate inspections and tests that are necessary to confirm that the product made for GENMARK meets all of its specified requirements and quality attributes.  
  
C. Standard operating procedures. Production operations are to be defined, conducted, controlled, and monitored to the extent necessary to ensure that the product made for GENMARK conforms to its specifications. This is to be documented in standard operating procedures (SOP’s).  
  
D. Production controls. A process control plan (or similar document) shall be established and maintained that outlines the various production operations and the process controls necessary to manufacture acceptable product for GENMARK, if not already detailed and included in the process plan. The following is a list of items that must be considered for inclusion in the process control plan, dependent upon, and where appropriate for, the complexity of the process(es) used to manufacture product for GENMARK.  
1.  
The controls to assure only accepted process inputs are used. Inputs are the materials and parts needed to make the product.  
2.  
Clear identification (labeling) and separation of the materials and parts stored on the production floor in order to prevent mix ups and their unintended use.  
3.  
Controls to prevent the use of materials that have exceeded or are nearing their expiration date.  
4.  
The process to ensure the production line has been cleared of inputs from previous production runs for a different product (i.e., a “line clearance”).  
5.  
The assignment of a unique lot or batch number, or date code, to the production run for future reference and record keeping.  
6.  
The manufacturing steps required (i.e., the use of a route tag).  
7.  
The criteria for workmanship, including representative samples.  
8.  
The process characteristics (parameters) to be controlled during production.  
9.  
The means, such as SPC, for the continuous monitoring and control of critical-control-points in the production processes.  
10.  
The in-process product attributes that are critical to quality are monitored during production.  
11.  
The defined acceptance and rejection criteria of the process output to ensure that they are correctly inspected/tested by qualified individuals.  
12.  
Controls for the handling and reworking of in process nonconformances.  
13.  
The final inspection and test methods to be used for product release.  
14.  
Handling procedures to assure that personnel handling and moving both in-process and final product do not inadvertently cause nonconformances.  
15.  
The procedure for adequately packaging the product for shipment to GENMARK so that it is reasonable to expect that product quality will not be affected during transportation.  
16.  
The method for recording process data and inspection/test results either electronically or on paper forms.  
  
E. Automated test systems. Software controlled and/or automated test systems used to determine the acceptance or rejection of incoming product, in-process product or final product are to be validated or otherwise verified to assure that consistent and repeatable results are obtained and that the system is fit for its intended use.  
  
F. Process validation. Where the results of a process cannot be fully verified by subsequent inspection and test, the process shall be validated. Processes that typically require validation include, but are not limited to:  
Reflow & wave soldering  
Injection molding  
Plating  
Bonding  
Sterilization  
  
GENMARK shall be responsible for the software validation (current and future revisions) of any embedded product software and the validation of all GENMARK -supplied: (1) test equipment or test software; (2) production equipment or software; and  
  
  
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(3) firmware. Plexus is responsible for the validation of any Plexus software used in production in, or as part of its quality system.  
  
G. In-process rejects. Supplier is to establish and maintain procedures to ensure that the causes of internal, in-process rejects are identified and corrected so as to prevent their recurrences. Where appropriate, supplier shall monitor (i.e., trend chart analysis) production operations to enable the early detection of problems and correct them in order to prevent rejects from occurring.  
  
H. Statistical applications. Valid statistical techniques shall be used, where appropriate, for the verification of the acceptability of incoming product, process characteristics, and product release.  
  
I. Environmental controls. Where environmental conditions (temperature, humidity, ESD, etc.) could reasonably be expected to have an adverse effect on quality, the supplier shall establish and maintain procedures to adequately control these environmental conditions. Maintenance schedules and activities must be documented.  
  
J. Equipment maintenance. Production equipment is to be maintained to ensure its continuing suitability and capability to manufacture acceptable output.  
  
K. Final acceptance activities. Product shall not be released for shipment until all requirements have been confirmed as being satisfactorily completed, unless otherwise approved in writing by GENMARK. Records shall include the signature of the person(s) authorizing release of the product. Prior to shipment, the supplier shall confirm and document that the product meets all of its requirements. This verification is to include the following items.  
1.  
The GENMARK part number and revision level to be shipped is what was ordered.  
2.  
The process control plan was followed. All in-process inspection and tests and final inspections and tests were completed and their results are acceptable.  
3.  
All required forms and other documents are available and correctly completed.  
4.  
Any necessary documents to be shipped with the product, such as a certificate-of-conformance, are complete and ready to go.  
  
L. Production history records. Records, including route tags, process forms, inspection forms, and test data forms, are be maintained to demonstrate that the product was produced according to the production control plan.  
  
3. Storage, packaging and transport  
  
The supplier shall ensure that sufficient protection is given for storage on its own premises, in particular against damage and environmental influences.  
GENMARK is responsible for defining and validating the finished device packaging. GENMARK will provide Plexus with written certification that the packaging validation has been performed prior to the production of the devices.  
  
To the extent the parties do not have any other agreement relating thereto, the products shall be packaged and transported in a defined and reproducible manner at the supplier’s responsibility. The supplier shall thereby ensure that the packaging units are clean, that there is sufficient protection in place against damage and that the transport security in place is capable of maintaining the quality requirements.  
  
As far as possible, the environmental impact of packaging and transportation of newly produced products by way of coordinated forwarding concepts with multiple and/or shuttle packaging, the reduction of the packaging volume and use of environmentally friendly packaging materials, as well as the costs of packaging and disposal, are to be optimized.  
With regard to packaging repaired used products and spare parts, single shipment packages are to be used that can only be opened by way of a sealed closure, and which are suitable with regard to providing effective protection against transport-related changes in the case of worldwide shipment. The possibilities with regard to reducing the amount of packaging, and the use of environmentally friendly materials and reusable packaging, are to be utilized insofar as such course of action is also possible within this framework.  
  
4. Nonconformances  
  
A. Control of nonconforming articles. Nonconforming articles (raw materials, parts, piece parts, in-process work, etc., used to produce product for GENMARK that do not meet specified requirements) are to be rejected, labeled as such, and separated to preclude their accidental use. Nonconforming articles can only be used to produce product for GENMARK after they have  
  
  
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been reworked to meet original specifications, or with written (e.g., deviation) authorization from GENMARK.  
  
B. Control of nonconforming product. Product made for GENMARK that failed to meet its specified requirements and quality attributes shall be rejected, labeled as such, and separated so as to prevent it from being shipped to GENMARK. Supplier shall not knowingly ship nonconforming product to GENMARK without first receiving written authorized approval from GENMARK.  
  
C. Rework of nonconforming product. Nonconforming product may be reworked provided these operations are carried out according to written procedures and are carried out by personnel having the necessary knowledge and skill sets to perform the rework. Reworked product must be re-inspected and re-tested, and pass all originally specified requirements and quality attributes. The rework operations, including the reinspection and retests, are to be recorded.  
  
D. Product returns. Suppliers must have a procedure for receiving returned product from GENMARK in the event it is rejected. The supplier’s procedure should include verification of the nonconformance. If the nonconformance cannot be verified, for whatever reason, the supplier shall promptly notify GENMARK and work toward a resolution. When the nonconformance is confirmed by the supplier, appropriate corrective action is to be taken to address and correct the problem. This action may include:  
1.  
Confirming that the correct process inputs were used.  
2.  
Confirming there was an adequate “line clearance” before making the product for GENMARK.  
3.  
Verifying personnel are adequately trained and have the necessary skill sets.  
4.  
Changing the process plan (i.e., increasing in-process and/or final inspections and tests, moving controls upstream in the process for earlier detection of problems, instituting new inspections or testing, etc.).  
5. Modifying the production control plan (i.e., increased in-process monitoring of process parameters).  
6. Reworked or returned product subsequently reshipped to GENMARK is to be clearly labeled or otherwise identified as being reworked or repaired, and packaged in all new materials.  
  
E. Product salvaging. New products may only contain components drawn from used products if expressly approved by GENMARK.  
  
  
  
5. Processing product changes of manufactured product  
  
The supplier shall document all product changes in accordance with its quality management system. This includes, but is not limited to, product changes that could have an effect on product function; design; acceptance; interfaces; transport and storage capabilities; handling; capabilities regarding processing, repairs or maintenance; production processes; recycling or the disposal of products as well as all changes to documents that are distributed with the products (e.g. data sheets, operating manuals or maintenance instructions).  
  
A. Processing product changes initiated by the supplier. All product changes by the supplier are subject to written approval by GENMARK. For approval, the supplier shall forward to GENMARK a written change inquiry, which shall address the following points:  
•  
Products and product characteristics affected  
•  
Exact description of required change  
•  
Consequences of product change from the supplier’s point of view (including risks)  
•  
Required start of product change (e.g. from serial number, batch number, order or date).  
•  
GENMARK shall assess the required product change and provide the supplier with written authorization, which may be subject to further requirements.  
  
B. Implementing product changes initiated by the supplier. The supplier shall only implement the changes following the receipt of the written authorization by GENMARK of the changes and the implementations of any further requirements contained therein, and provide notification of the conclusion of the implemented changes in the form of a written confirmation to GENMARK.  
  
Following the successful validation of the change, at the supplier’s premises or, if necessary at GENMARK’ premises, the delivery of the changed products shall be released in writing by GENMARK.  
  
The start of the delivery of changed products shall be agreed upon in writing.  
  
  
  
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C. Processing product changes initiated by GENMARK. If GENMARK requests a change in the product, GENMARK shall forward a written change inquiry to the supplier, which shall address the following points:  
•  
Products and product characteristics affected  
•  
Exact description of required change  
•  
Consequences of product change from GENMARK point of view (including risks)  
•  
Required start of product change (e.g. from serial number, batch number, order or date).  
  
The supplier shall review the degree to which the requested changes can be realized and the consequences, and inform GENMARK of the outcome of such a review in the form of a written offer.  
  
Following the review of such an offer, GENMARK shall issue the supplier with a written change order, including the respective validation requirements. Within such a change order the costs and the release regarding the manufacture of an initial batch or a prototype shall be agreed upon.  
  
D. Supplier implementing changes initiated by GENMARK. The supplier shall implement the product change following the receipt of the written change order and the parameters specified therein by GENMARK, and provide notification of the conclusion of the implementation of the change in the form of a written change confirmation. The supplier shall furthermore make available to GENMARK prototypes of the changed products against reimbursement of its costs if this is necessary for further validation at GENMARK’ premises.  
  
Following the successful validation of the product change, at the supplier’s premises or, if necessary at GENMARK’ premises, the delivery of the changed products shall be released in writing by GENMARK.  
  
The start of the delivery of the changed products shall be agreed upon in writing.  
  
In the event of any conflict between this Section 5 of the QAA and the Supply Agreement, the Supply Agreement shall control.  
  
  
  
  
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Annex II. Specific Requirements for  
Warehousing/Distributing Product for GENMARK  
  
A. Handling. The supplier shall have controlled processes to ensure that only product authorized by GENMARK is received, stored and distributed. The process is to include a method that prevents mix-ups, damage, deterioration, contamination, or other adverse effects from occurring to product during handling. Records of receipts, including the date and name of person accepting the receipt, shall be maintained.  
  
B. Storage. The supplier shall have processes that ensure control of storage areas and stock rooms for product to prevent mix-ups, damage, deterioration, contamination, or other adverse effects pending use or distribution and to ensure that no obsolete, rejected, or deteriorated product is used or distributed. When the quality of product deteriorates over time, it shall be stored in a manner to facilitate proper stock rotation, and its condition shall be assessed as appropriate.  
  
C. Product packaging. The supplier is responsible for and shall ensure that device packaging and shipping containers are used to protect the device from alteration or damage during the customary conditions of processing, storage, handling, and distribution.  
  
D. Distribution. The supplier shall control the distribution of product to ensure that only product approved for release are distributed and that purchase orders are reviewed to ensure that ambiguities and errors are resolved before products are released for distribution. Where a product’s fitness for use or quality deteriorates over time, the controls shall ensure that expired products are not distributed.  
  
E. Distribution records. The supplier shall maintain distribution records and make them available to GENMARK upon request. Records are to include:  
1. The name and address of the initial consignee;  
2. The identification and quantity of devices shipped;  
3. The date shipped; and any control number(s) used.  
  
F. Reserved.  
  
G. Environmental controls. Where environmental conditions (temperature, humidity, ESD, etc.) could reasonably be expected to have an adverse effect on quality, the supplier shall establish and maintain procedures to adequately control these environmental conditions. Maintenance schedules and activities must be documented.  
  
  
  
  
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Annex III. How GENMARK Evaluates Its Suppliers  
  
A. Introduction. Those suppliers identified based on annual spend or those suppliers whose products and/or services are critical to the safety, efficacy, and reliability of the medical devices GENMARK manufactures, will be deemed “Class 1suppliers, and will be evaluated by GENMARK in accordance to GENMARK Quality Procedure QP0800.  
  
B. Details of the GENMARK Evaluation System.  
  
1.  
Purchasing  
a.  
Total Cost Performance  
i.  
Are supplier’s prices competitive?  
ii.  
Payment terms  
iii.  
Additional procurement costs  
b.  
Cost Reduction Efforts  
i.  
Cost reduction efforts within existing designs  
c.  
Fulfillment of Strategic Requirements  
i.  
The market strategy of the supplier  
ii.  
How is the supplier’s economic situation?  
iii.  
How is the conduct during contract negotiations?  
iv.  
Supplier is registered in Click4Suppliers (c4s)  
v.  
Does the supplier offer an Open Book Policy?  
d.  
Co-Operation, Service, & Support  
i.  
Cooperation, Service, & Support  
2.  
Quality  
a.  
Quality Performance  
i.  
Product Acceptance Quality Performance (includes Receiving, In Process, Service, Reporting and Documentation, Packing, etc.)  
ii.  
Field Quality Performance After Delivery (or similar measure; e.g. Open MPSR ratio)  
b.  
Quality System  
i.  
Does the supplier have a Quality Management System (QMS) which meets the requirements of GENMARK or the business unit?  
ii.  
Quality Management System, audit findings  
iii.  
Number of corrective and preventative action (CAPA) or supplier development plans  
c.  
Quality Assurance Agreements (QAA)  
i.  
QAA in place or part of the frame contract, as appropriate  
d.  
Co-Operation, Service, & Support  
i.  
Cooperation, Service, & Support  
3.  
Logistics  
a.  
Logistics Performance  
i.  
Does the supplier meet targeted delivery/milestone dates?  
ii.  
How good is the response time to delivery problems  
iii.  
Delivery flexibility  
b.  
Logistics Strategy and System  
i.  
Does the supplier offer logistics models which meet the needs and requirements of the business unit  
ii.  
Interface connection  
c.  
Environmental Aspects  
i.  
Does the supplier have an EMS which systematically advances the improvement of environmental protection and keeps GENMARK informed about current actions for environmental protection?  
ii.  
Does the supplier meet the requirements of the ecological product/service design, packing, and logistics?  
iii.  
Documentation of hazardous materials  
d.  
Co-Operation, Service, & Support  
i.  
Cooperation, Service, & Support  
4.  
Technology  
a.  
Current technology position  
i.  
Product technology (“Product” also means Service and Software)  
ii.  
Engineering capability and competence  
iii.  
Engineering documentation  
iv.  
Technical equipment and facilities  
  
  
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b.  
Fulfillment of specific technical requirements  
i.  
Prototypes and engineering samples  
ii.  
Supplier communication and support of changes  
c.  
Fit of technology roadmaps  
i.  
The supplier’s technology roadmap includes research, design, manufacturing processes, environmental health and safety characteristics  
d.  
Co-Operation, Service, & Support  
i.  
Cooperation, Service, & Support  
ii.  
Support of manufacturing and/or sustained engineering  
  
  
  
  
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IN WITNESS WHEREOF, the parties hereto have executed this Quality Agreement as of the Effective Date:  
  
  
CLINICAL MICRO SENSORS, INC. Plexus Corp.  
D.B.A GenMark DIAGNOSTICS, INC.  
  
  
By: /s/Xxx Xxxx By: /s/ Xxxxxx Xxxxxxxxx  
Name: Xxx Xxxx Name: Xxxxxx Xxxxxxxxx   
Title: Director Quality Assurance Title: Quality Engineer   
  
  
By: /s/ Xx Xxxxxxxx By: /s/ Xxxxx Xxxxxxx  
Name: Xx Xxxxxxxx Name: Xxxxx Xxxxxxx  
Title: VP QA and Regulatory Affairs Title: Mgr - Regulatory Compliance   
  
  
  
  
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Exhibit B  
Specifications  
  
Document No.  
Description  
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\*\*\* Portions of this page have been omitted pursuant to a request for Confidential Treatment and filed separately with the Commission.   
  
Exhibit C  
Products and Pricing  
  
Effective Date Beta Pricing  
  
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Production Product Pricing Criteria  
  
The parties agree that:  
Prior to manufacturing Product production units under this Agreement and consistent with past practice, Plexus will provide GenMark with \*\*\* . (collectively, the “Pricing Criteria”).  
  
  
  
  
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Exhibit D  
GenMark Equipment  
  
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