Effective Date: _____ __, 20__

Bluepoint Medical GmbH & Co. KG , a corporation organized under the laws of Germany ("Supplier") provides goods, including parts, and/or services ("Product(s)"). As of the Effective Date, Supplier and General Electric Company, acting through its GEHC division, ("GEHC"), agree to the following. Notwithstanding anything to the contrary, GEHC is under no obligation to purchase, and Supplier is under no obligation to provide, any Products from Supplier as a result of signing this document.

The term "Finished Medical Device" (or "FMD"), as used herein, are Products that also constitute finished medical devices under the Federal Food, Drug and Cosmetic Act ("FDCA") and/or any other applicable country laws or equivalent regulatory bodies where the Products(s) is manufactured or shipped or sold by GEHC or on GEHC's behalf.

"Supplier FMD" are Products that constitute FMD, and Supplier: (i) owns the Product design specifications; (ii) sells the Product to GEHC with or without GEHC's logo or trademark; (iii) sells the Product to GEHC with or without GEHC-required customization (provided that such customization does not violate the restrictions of Supplier's regulatory approvals and does not substantially change the Product); (iv) owns and maintains any regulatory registrations, approvals, and/or licenses required under applicable laws or regulations to lawfully market the Product; and (v) manufactures and commercially distributes the Product (notwithstanding GEHC may be the importer of the Product to GEHC's final customer).

"GEHC FMD" consists of those Products that constitute FMD, and: (i) GEHC owns or controls the Product design specifications; (ii) GEHC owns and maintains any regulatory registrations, approvals, and/or licenses required under applicable laws or regulations to lawfully market the Product; (iii) Supplier manufactures the Product and either GEHC or the Supplier commercially distributes the Product; and (iv) GEHC markets the Product.

All references herein to "Products(s)" include Supplier FMD and GEHC FMD.

The term "part," as used herein, indicates the hardware, software, chemicals, equipment, materials, and/or services being purchased.

1.0 Quality System

1.1 Quality Management System. Supplier shall document, implement, and maintain a mutually acceptable quality system. The ISO9001 system or equivalent certifications are examples of an acceptable quality standard. Upon request from GEHC, Supplier shall provide documented corrective action plans within thirty (30) days from receiving a corrective action request from GEHC; such corrective action plan is subject to GEHC's written approval. Should Supplier fail to correct the Product quality problem within a time period that is acceptable to GEHC, GEHC may, at its discretion, terminate any unfulfilled Agreement(s) with respect to the affected Product(s) notwithstanding anything to the contrary herein or therein in addition to any other rights or remedies available to GEHC at law or in equity.

1.2 Electrostatic Discharge. If Electrostatic Discharge (ESD) sensitive Products are supplied to GEHC, Supplier must have an active ESD program and use appropriate ESD handling and packaging procedures. Examples of acceptable ESD programs are documented in IEC 61340-5-1, Protection of electronic devices from electrostatic phenomena - General requirements or ANSI/ESD S20.20, For the Development of an Electrostatic Discharge Control Program -for – Protection of Electrical and Electronic Parts, Assemblies, and Equipment (Excluding Electrically Initiated Explosive Devices). Supplier must maintain written records of the testing and training performed.

1.3 Audit Rights. At GEHC's written request, Supplier will allow GEHC (directly or through third parties) to audit and inspect Supplier's quality management system, as well as all other records that Supplier is required to maintain hereunder, at periodic intervals, as well as copy all documents that GEHC deems are necessary to ensure Products provided to GEHC meet or exceed GEHC's requirements. GEHC may also request periodic, joint quality assurance meetings at the Supplier's facility to update the status of Product quality and reliability.

2.0 Quality Record Retention

2.1 Acceptance Activities for GEHC FMD. - N/A

2.2 Acceptance Activities for Supplier FMD. For Supplier FMD, Supplier shall maintain all documentation required by the U.S. Food and Drug Administration (FDA) and any other country or equivalent regulatory body where the Supplier FMD is shipped or sold on by GEHC or on GEHC's behalf.

2.3 Acceptance Activities Records for Products That Do Not Constitute FMD. - N/A

2.4 GEHC Document Warehousing and Retrieval. - N/A

3.0 Compliance

Supplier shall comply with the terms of the Agreement. Supplier shall maintain compliance with the laws and government regulations that apply in the manufacturing, servicing, distribution and delivery of the Products. Such laws may include, but are not limited to, regulations and directives, labor laws, environmental laws, Custom Trade Partnership Against Terrorism (CTPAT) and product safety laws. Supplier shall provide GEHC all information that GEHC requests that is necessary in GEHC's opinion to enable GEHC to comply with the laws and regulations applicable to GEHC's sale and use of Products. Supplier shall maintain compliance to all applicable industry standards and product listings for all Products delivered to GEHC.

4.0 Change Notification

4.1 GEHC Proposed Product Changes. GEHC may propose changes to any of the Products by submitting such changes to Supplier. GEHC will identify those changes that it deems mandatory in order to make the Product suitable for GEHC's intended use. Unless otherwise agreed to in writing by GEHC, Supplier will respond in writing to GEHC within ten (10) days after receipt of such proposed or mandatory changes with the following information, as applicable: (i) lead time required to implement the changes; (ii) impact of changes on Product, including, but not limited to, any parts, tooling, and testing; (iii) impact of changes on scrap material and work in process; (iv) any non-recurring engineering changes to implement the changes; and (v) impact of changes on the lead time of the Product.

4.2 Supplier Proposed Product Changes. - N/A

4.3 Supplier Proposed Product Changes to Supplier FMD. Notwithstanding anything to the contrary and with respect to Supplier FMD, any and all changes proposed by Supplier, including material, process, or software changes, which may affect customer specifications (technical notice), regulatory compliance, or interface capability of Supplier FMD must be submitted along with a written change notice, for GEHC's written approval. This includes, but is not limited to, manufacturing locations. Supplier FMD affected by such changes will not be delivered to GEHC until Supplier has received written approval for the changes from GEHC. At minimum, the Supplier's written change notice must include the affected Supplier FMD, date of implementation, specific details of the change, and, if available, supporting data that demonstrates that Supplier FMD reliability has not been impacted negatively. In addition, Supplier (at GEHC's request) agrees to furnish at no charge Supplier FMD samples for evaluation prior to approval by GEHC of such changes.

4.4 Supplier Proposed Product Changes to GEHC FMD. - N/A

5.0 Part Controls

5.1 Purchasing Specifications.

(a) Supplier shall meet the part requirements and specifications as referenced in the Agreement. Supplier is accountable to ensure that delivered Products meet the requirements of the revisions and/or versions specified in the applicable Agreement. Supplier shall not accept nor implement any GEHC part/product concession without documented prior written approval from GEHC. Supplier shall clearly mark each shipment containing the part/product under GEHC concession. Upon concession expiration or closure, whichever occurs first, no additional part/product under the concession shall be shipped to GEHC. Where applicable, Certificates of Conformance (COCs) or Certificates of Acceptance (COAs) must be on file at the Supplier's location and submitted to GEHC upon request and per the requirements of the purchasing specification. If product is re-worked or repaired, a new COC/COA must be issued.

Supplier shall ensure that GEHC documentation is controlled and distributed with the current and correct revision level only to authorized employees on a need-to-know basis that manufacture the Product for GEHC. Such documentation is proprietary and confidential information of GEHC. Supplier shall ensure that all GEHC documentation is held in trust and confidence for the sole and exclusive benefit of GEHC, and not disclosed to any third parties except as provided below. Supplier is responsible for ensuring that no restrictive or proprietary marks are removed or modified from any GEHC documentation.

(b) For all Products, Supplier is responsible for ensuring that applicable GEHC documentation is provided to Supplier's sub-suppliers and used by them solely for purposes of supplying Products to GEHC. Supplier shall ensure that Supplier, as well as its subcontractors that use GEHC purchasing documentation, maintain such documentation in compliance with all accepted Engineering Change Requests/Engineering Change Orders issued by GEHC. Supplier will ensure that it has written agreements in place with each of its sub-suppliers that are consistent with the terms contained in Section 5.1(a).

(c) Supplier receives no rights or licenses to any GEHC information or documentation, and none will be implied.

5.2 Product Qualification. - N/A

5.3 Packaging and Shipping Methods. Supplier shall provide packaging and shipping methods to prevent contamination; degradation; and cosmetic, mechanical, and electrical damage to the Product. Supplier shall meet the detailed specifications of the GEHC packaging requirements found in the GEHC purchase specification and per international shipping regulatory and customs requirements.

5.4 Part Authenticity. - N/A

5.5 GEHC-Directed Sub-tier Vendors.

5.5.1 In the event that GEHC directs in its parts requirements and specifications that some or all of the GEHC components be purchased from third party vendors or distributors (sub-tier vendors), Supplier will purchase said components only from these directed sub-tier vendors. Supplier shall not substitute alternative sub-suppliers without GEHC's prior written approval per section 4.2.

5.5.2 Supplier shall qualify and monitor GEHC directed sub-tier vendors per Supplier's internal purchasing controls procedures, including, but not limited to, supplier qualification; component performance monitoring; and corrective action and preventive actions.

6.0 Supplier FMD Requirements

6.1 Continuing Guarantee for Supplier as required by the FD&C Act. The articles comprising each Supplier FMD shipment for delivery hereafter made by Supplier or on the order of GEHC are hereby guaranteed by Supplier as of the date of shipment or delivery to be on that date: (a) manufactured and released as finished devices in accordance with the applicable provisions of the FDCA as amended (21 U.S.C. section 301 et seq.) relating to adulterated or misbranded devices; (b) not an article prohibited under the provisions of sections 501 or 502 of the FDCA from being introduced into interstate commerce; (c) in compliance with the provisions of sections 510, 513, and 515 of the FDCA. This guarantee is continuing and shall remain in full force and effect.

6.2 Product Certification.

6.2.1 Supplier shall manufacture and label Supplier FMD in strict conformance with all applicable requirements and regulations, including e.g. CE Marking, FDA, ISO13485, or equivalent applicable regulatory body, each as may be modified from time to time, and maintain the same. Unless agreed to otherwise in writing, if a party proposes a change in purchase specification, that party shall be responsible for any additional Supplier FMD certification or regulatory approval costs that may be necessary.

6.2.2 Upon GEHC's request, Supplier shall provide GEHC, GEHC's notified body, or the appropriate regulatory authority, with a copy of all regulatory certification reports including, but not limited to, technical documentation (set up according to Annexes II.4, or III from EU Directives 90/385/EEC-93/42/EEC; Annexe VII from Directive 93/42/EEC as amended with 2007/47/EC; the annexe from Directive 2003/32/CE; and Annexe III from Directive 98/79/CE). Supplier shall also comply, at its own costs, with the international quality standard ISO13485, as may be modified from time to time.

6.2.3 - N/A

6.3 Provision of Regulatory and Safety Information by Supplier. Supplier shall, at the request of GEHC, provide GEHC with the following information relating to the Supplier FMD, at no cost to GEHC:
(i) All relevant information on product safety, efficacy, reliability and performance characteristics; and
(ii) Copies of all U.S. and foreign regulatory submissions, notifications, licenses, labeling, clearances, and approvals, including any 510(k) submissions and clearances, held by Supplier for the Supplier FMD.

6.4 Regulatory Approvals and Other Governmental Registrations. Registration responsibilities are defined per a separate target market agreement. Supplier is responsible for identifying, obtaining, and maintaining all applicable clearances and approvals that are required for the development, manufacture, or sale of any Supplier FMD in countries where the product is shipped or sold. Supplier represents and warrants that it has obtained all such approvals for any Supplier FMD existing as of the Effective Date. For countries which Supplier does not hold regulatory approvals, test reports and all necessary data to meet the country specific regulatory requirements have to be prepared and made available to GEHC on request, and Supplier shall apply or assist GEHC regarding all governmental registrations required for GEHC to market Supplier FMD as a distributor or importer in such countries as defined in the target market agreement. Supplier shall reasonably cooperate with GEHC in its efforts to obtain such approvals. Supplier agrees that GEHC shall have access to all of Supplier's non-confidential regulatory submissions for the Supplier FMD to the extent necessary to exercise its rights or fulfill its obligations hereunder.

6.5 Complaint Handling. Supplier will be responsible for the coordination of customer complaint investigations pertaining to Supplier FMD. As determined by GEHC, Supplier will investigate customer complaints at no charge and supply GEHC with a written report summarizing the cause for the complaint and any corrective actions required within 14 days of receipt by Supplier of such complaint, it being understood that, depending on the nature of the complaint and investigation, the initial (14-day) response may be limited in scope and then followed up by a complete response as soon as reasonably practicable thereafter.

6.6 Duty to Report Incidents. Supplier shall inform GEHC in writing, within five business days from knowledge of a reportable event, of all incidents relating to the subject matter of the Agreement that must be reported according to the FDA Medical Device Reporting regulation (21 CFR Part 803); CFDA regulations; MHLW regulations; or the European Medical Device Vigilance regulations or that must be registered according to other national regulations such as Canadian Medical Device Regulations, including without limitation incidents involving death or serious injury, malfunctions that, if recurrent, may cause or contribute to death or serious injury or other material quality problems or concerns. Supplier will be responsible for reporting such incidents to the appropriate regulatory authority. Supplier shall fully cooperate with GEHC as may be necessary to comply with any GEHC reporting obligations as an importer or distributor regarding such incidents or quality concerns.

6.7 Recalls and Field Corrections. In the event of any recall, withdrawal or field correction of any Supplier FMD that is required by a governmental agency, Supplier, or GEHC for safety, regulatory, quality, or efficacy reasons, the parties agree that (a) they shall promptly notify each other and (b) they shall fully cooperate with each other concerning the necessity and nature of such action. Supplier shall provide in a timely manner a solution for the affected product to be corrected or removed. Supplier shall be the point of contact for purchasers of any Supplier FMD (whether directly or through its distributors), and shall be responsible for making any and all applicable regulatory authority contacts and for coordination of any recall or field correction activities involving such Supplier FMD, whether or not such action was requested by Supplier. Recall and field correction activities may include, but are not limited to, communications and meetings with all required regulatory agencies, replacement stock, service labor, installation, travel, notifying customers of such recall and any replacement product to be delivered to those same customers, including shipping. In countries where the importer is required by regulation to report recalls to the regulatory agency, the Supplier shall fully cooperate with GEHC to provide the necessary information in a timely manner in order for GEHC to prepare and file the report with the regulatory agency in a timely manner.

6.8 Regulatory Agency Inquiries. If the FDA or any other regulatory body with authority over medical devices provides written notice to either party to inquire about or investigate any Supplier FMD or conduct any inspection or audit of facilities used for the manufacture, storage or distribution of Supplier FMD or request any information related to the manufacture of any Supplier FMD, the party notified shall notify verbally and in writing within one working day of receipt of such contact from the FDA or other body. Supplier shall notify GEHC of any non-conformances related to GEHC FMD received from any regulatory agency within 3 working days.

6.9 GEHC as an Own Brand Labeler. - N/A

6.10 Software Suppliers. - N/A

7.0 GEHC FMD Requirements - N/A

7.1 Regulatory Approvals and Other Governmental Registrations. - N/A
7.2 Regulatory Agency Inquiries. - N/A
7.3 Subcontractors. - N/A
7.4 Supplier Use of Approved Vendors/Brokers. - N/A
7.5 Design History File/Device Master Record. - N/A
7.5.1 Design and Development. - N/A
7.5.2 Device Master Record. - N/A
7.5.3 Product Release and Distribution. - N/A
7.5.4 Labeling and Packaging. - N/A
7.6 Complaint Handling. - N/A
7.7 Duty to Report Incidents. - N/A
7.8 Recalls and Field Corrections. - N/A
7.9 Software Suppliers. - N/A

8.0 Product Sterilization Requirements - N/A

8.1 Sterilization Standards. - N/A
8.2 Supplier and Process Controls. - N/A
8.3 Verification and Validation Process Controls. - N/A
8.4 Subcontractors. - N/A
8.5 Sterilization Audit Rights. - N/A
8.6 Shelf Life. - N/A
8.7 Shipping Conditions. - N/A
8.8 GEHC Labeled Sterile Product. - N/A
8.8.1 Specifications. - N/A

8.8.2 Qualification Protocols. - N/A
8.8.3 Lot Release. - N/A
8.8.4 Lot Verification. - N/A
8.8.5 Product Validation. - N/A
8.9 Supplier Labeled Sterile Product. - N/A

9.0 Equipment Calibration Service Providers - N/A

9.1 Calibration Performance Verification and Optimization. - N/A
9.2 Compliance to Quality Requirements. - N/A
9.3 Notification of Out of Tolerance Standards. - N/A
9.4 Calibration Records. - N/A
9.5 Reporting. - N/A
9.6 Subcontractors. - N/A

10.0 Service and Installation - N/A

10.1 Service and Installation of GEHC Product. - N/A
10.2 Service and Installation of OEM Products. - N/A
10.3 Complaint Reporting. - N/A
10.4 Calibration and Maintenance. - N/A
10.5 Service Reporting. - N/A
10.6 Subcontractors. - N/A

11.0 Controlled Environment and Clean Room Service Providers - N/A

11.1 Room Design. - N/A
11.2 Room Controls and Maintenance. - N/A
11.3 Particle Monitoring. - N/A
11.4 Microorganism Monitoring. - N/A
11.5 Alternative Tests. - N/A
11.6 Room Operations and Workforce. - N/A
11.7 Separative Devices (e.g., clean air hoods, glove boxes, isolators, mini-environments). - N/A

12.0 Bovine Spongiform Encephalopathy/Transmissible Spongiform Encephalopathy ("TSE") - N/A

13.0 Repair and Remanufacturing - N/A

13.1 Repair and Remanufacturing of GEHC FMD at Supplier Site. - N/A
13.1.1 Regulatory Approvals and Other Governmental Registrations. - N/A
13.1.2 Regulatory Agency Inquiries. - N/A
13.1.3 Calibration and Maintenance. - N/A
13.2 Repair of GEHC Designed Parts at Supplier Site. - N/A

14.0 Finished Product Requirements - N/A

14.1 Product Certifications. - N/A
14.2 Governmental Registrations. - N/A
14.3 Recalls and Field Corrections. - N/A
14.4 Software Suppliers. - N/A
14.5 Design and Development. - N/A

15.0 Applications Specialists - N/A

15.1 Certifications. - N/A
15.2 Complaint Reporting. - N/A
15.3 Maintenance of records. - N/A
15.4 Promotion of off-label use. - N/A
15.5 GEHC Quality Policy. - N/A
15.6 Training and Certification. - N/A

16.0 Clinical Research - N/A

16.1 Clinical Investigators. - N/A
16.1.1 Certifications. - N/A
16.1.2 Restrictions/Disqualification. - N/A
16.1.3 Regulatory Compliance. - N/A
16.1.4 Regulatory Agency Inquiries. - N/A
16.2 Ethics Committees (Institutional Review Boards) - N/A
16.2.1 Membership. - N/A
16.2.2 Regulatory Compliance. - N/A
16.2.3 Record Retention. - N/A
16.2.4 Regulatory Agency Inquiries. - N/A
16.3 Study Monitors/Study Statisticians - N/A
16.3.1 Certifications. - N/A
16.3.2 Maintenance of records. - N/A
16.3.3 GEHC Quality Policy. - N/A
16.3.4 Training and Certification. - N/A
16.4 Clinical Research Suppliers - N/A
16.4.1 Compliance. - N/A
16.4.2 Record Retention. - N/A
16.4.3 Training and Certification. - N/A
16.4.4 Regulatory Agency Inquiries. - N/A
16.5 Audit Rights. - N/A

17.0 External Handling of Demonstration, Evaluation, and Customer Loaned GEHC Products (Demonstration Product) - N/A

17.1 GEHC Product Demonstration Program Management. - N/A
17.2 GEHC Product Segregation. - N/A
17.3 Personnel. - N/A
17.4 Electronic Data Systems. - N/A
17.5 GEHC Product Service, - N/A
17.6 Quality Management System. - N/A
17.7 Audit Rights. - N/A

18.0 General

This document, including a written Product purchase agreement signed by Supplier and GEHC that pertains to GEHC's acquisition of Products from Supplier, or in the absence of such an agreement, the terms and conditions of GEHC-issued purchase orders for Products that GEHC may issue to Supplier, (such written agreement or purchase orders are referred to herein as the "Agreement(s)") represents the entire understanding between the parties with respect to the subject matter addressed herein and GEHC's purchase of Products, if any, from Supplier. Without limitation to the foregoing, in no event will any different, supplemental, or conflicting terms of Supplier's invoices apply to any GEHC purchases of Product. In addition to any other rights or remedies available to GEHC at law or in equity (including those rights and remedies available to GEHC under any Agreement), it is understood that GEHC has the right to terminate (without any liability to GEHC) any Agreements with Supplier due to any failure by Supplier to comply with this document. Concerning the subject matter hereof, in the event of a conflict between this document and the applicable Agreement, this document will prevail. Only a written agreement signed by both parties can modify this document.

Agreed to and accepted by:

_____(Supplier)	GE Healthcare, a division of the General Electric Company (GEHC)
By:	By:
Signature: _____	Signature: _____
Printed Name:	Printed Name:
Title:	Title:
Date:	Date: