AGREEMENT. This purchase order and any supplemental terms and conditions or additional documents referenced in the body of the purchase order ("PO") constitute the only contract and understanding, whether oral or written, between Medtronic, Inc. or its affiliate issuing this PO ("MDT") and the party identified as Supplier on the face of this PO ("Supplier") for the goods, products or services ordered hereunder ("Products and/or Services"). Documents designated by MDT in the body of the PO, including supplemental terms and conditions, if any, are incorporated by reference the same as if set out in full therein and will form a part of the PO. Supplier acknowledges that no invoice, shrink-wrap, click-wrap, or other terms and conditions or agreement provided with any products or software shall be binding on MDT, even if use of such Products and software requires and affirmative acceptance and such terms shall be of no force or effect and shall be deemed rejected by MDT. To the extent MDT and Supplier are party to a valid, current, executed written agreement the scope of which includes the purchase of Products and/or Services that are the subject of this PO ("Agreement") then, the terms of such Agreement shall govern and control. If there is no such Agreement the terms and conditions of this PO shall govern. If there is an applicable Quality Agreement in place with the Supplier that shall govern first. All conflicting, different or additional Supplier terms are expressly rejected, and acceptance of this offer is expressly limited to the terms stated in this PO. No course of dealing or usage of trade or actual course of performance shall be relevant to explain or supplement any terms used herein. A MDT affiliate is an entity that directly, or indirectly through one or more intermediaries, controls or is controlled by, or is under common control with MDT.

QUANTITIES AND PRICE. The specific quantity ordered must be delivered in full and not be changed without MDT's prior written consent. Any different quantity without such consent is subject to MDT's rejection and return at Supplier's expense and MDT shall have no obligation for payment of any excess quantity. The price for the Products and/or Services shall be the price as indicated on the face of this PO. Any change in price without MDT's prior written consent and issuance of an amended PO is expressly rejected. No additional charges of any kind will be allowed except with MDT's prior written consent.

PAYMENT TERMS. Unless otherwise agreed, payment of an undisputed invoice shall be made via electronic funds transfer net 90 days from the date of receipt of an acceptable invoice. If MDT disputes all or a portion of an invoice, MDT may withhold such disputed amounts, and will promptly notify Supplier of the amount and reason for the dispute. All invoices must include the PO number and a detailed description of the Products and/or Services provided. MDT reserves the right not to pay any invoice issued more than 180 calendar days from the date originally required hereunder. All invoices shall be emailed as directed on the face of this PO. Fees are exclusive of applicable value-added, sales, use, excise, customs duties or other similar taxes ("**Taxes**"), relating to the sale, purchase, transfer of ownership, delivery, installation, license or provision of the Products and/or Services under the PO. MDT shall be responsible for the Taxes.

DELIVERY AND ACCEPTANCE. Time is of the essence in the performance of this PO, and any delay in delivery is a material breach. Title transfers to MDT upon delivery of the Products to MDT. Unless otherwise agreed, shipment of the Products shall be freight collect via MDT designated mode and carrier. If Supplier fails to comply, shipment is FCA destination with Supplier bearing the risk of loss and cost of delivery and MDT assumes no liability for loss or damage occurring prior to MDT's receipt. MDT is entitled to inspect the Products and/or Services (including the performance of tests) before or after receipt and reject them for failure to conform to this PO, regardless of whether any payment has been made by MDT, whether the nonconformity substantially impairs the value of the Products and/or Services, or whether the nonconformity may be cured by Supplier. MDT has the right upon reasonable notice to enter Supplier's facilities to inspect the production of Products and/or performance of Services, without precluding subsequent inspection and rejection of Products and/or Services. If the inspection discloses, in MDT's good faith opinion, that Supplier's ability to meet the requirements of this PO is questionable, MDT may treat such circumstance as a material breach and terminate this PO without liability to Supplier. If Products tendered pursuant to this PO are nonconforming, MDT may return all the Products to Supplier, at Supplier's expenses, for first priority repair, replacement or a refund at the election of MDT.

CONFIDENTIALITY. Supplier may not disclose to any third party (other than a government or judiciary body, as required by law, and only with prior written notice to MDT of any such disclosure), or use any information, including personal data, Supplier receives or learns about MDT or its affiliates in connection with or as a result this PO, including without limitation, the existence or details of this PO or any agreement or arrangement with MDT except as is necessary to perform this PO.



COMPLIANCE WITH LAW. Each party shall be responsible for ensuring that the performance of its respective obligations under this PO complies with all applicable local, state, federal, and international laws, rules, and regulations, whether in effect now or in the future (collectively, the "Laws"). Specifically, Laws shall include but not be limited to: TCPA, COPPA, FCRA, the Reform Act, HIPAA, privacy laws, environmental regulations, the FFDCA, and all international trade Laws, including but not limited to economic sanctions, anti-boycott, and Laws governing the import, export or any other transfer or provision of Products and/or Services. Additionally, Supplier shall adhere to all applicable laws relating to labor, environmental, health/safety and ethics, as well as MDT's Global Supplier Standards and any applicable MDT policies. Supplier may find more information online at (http://www.medtronic.com/about-medtronic/our-suppliers/responsible-supply-chain/index.htm).

INDEMNIFICATION. Supplier agrees to indemnify, defend and hold harmless MDT, its affiliates and their respective directors, officers, employees and agents from and against any and all fines, actions, suits, proceedings, claims, costs, liabilities, damages, losses, and expenses (including, but not limited to, reasonable attorneys' fees) arising out of or related to (i) any compensation owed to any employee of Supplier or any personnel for Services performed under this PO and for any tax, levy or other amount imposed with respect to such compensation and for any claims, damages or liability for injury or death to Supplier's personnel incurred in the performance of their duties; (ii) breach of Supplier's obligations under this PO; (iii) the allegations that the Products or Services infringe a third party's intellectual property rights or any other rights; (iv) acts or omission of Supplier or its personnel in performance of this PO; or (v) any negligent, fraudulent, or willful conduct by Supplier or its personnel.

REFERENCE. Supplier shall not use or display MDT's or its Affiliates names, logos or symbols, or other registrations, trademarks or service marks without the prior written permission of MDT.

SOFTWARE LICENSES. If software is provided under this PO Supplier grants a worldwide, perpetual, royalty-free license in favor of MDT and its affiliates for any use, including but not limited to, copying, accessing, and creating derivative works.

OWNERSHIP AND USE. All ideas, inventions, documents, work in progress, computer or other electronic data files, drawings, tooling, source code and other items prepared by Supplier or arising in connection with this PO ("Deliverables"), and all items furnished by or on behalf of MDT, shall be the property of MDT and no reproductions or property interest shall be retained by Supplier. To the extent allowed by law, copyrightable subject matter created by Supplier shall be deemed "work made for hire." Supplier agrees to assign and hereby assigns its rights in all Deliverables to MDT.

TERM/TERMINATION. This PO shall have a term of 1 year unless otherwise agreed by the parties. MDT may terminate this PO at any time without cause upon 5 days written notice to Supplier. Either party may terminate this PO immediately if the other party materially breaches this PO which is not cured within 30 days of receipt of written notice of the non-breaching party's intent to terminate. In the event of termination, MDT's liability shall be limited to the price of, and Supplier shall deliver to MDT, Products and/or Services scheduled for delivery and/or performance during the period ending on the date notice of termination is received.

CHANGES. MDT is entitled to change the specifications for the Products and/or Services or any other matters relating to performance of this PO at any time. Supplier shall not make any change to the Products or deviate from the Services covered by this PO, without MDT's prior written consent. Upon approval by MDT of the initial design, any process changes, design changes or deviations considered by the Supplier must be submitted to MDT in writing for review. If changes are submitted for approval, the information submitted must include a complete description of the change and the effect the change will have on all characteristics of the Products and/or Services. Upon request, Supplier shall submit samples of the Products for evaluation and approval by MDT.

WARRANTIES. Supplier warrants that (i) the Products and/or Services will be in accordance with the specifications, drawings and other instructions attached to this PO or to which MDT and Supplier subsequently agree in writing; (ii) the Products do not infringe upon any third party's intellectual property, including patents, copyrights, trademarks or trade secrets; (iii) Supplier has all necessary rights to sell or license the Products; (iv) any software or hardware provided by Supplier to MDT under this PO does not contain any unauthorized code or other device, include but not limited to viruses, worms, time bombs, time locks, drop-dead devices, access codes, security keys, back doors, or trap door devices, that is designed to disrupt, disable, erase, harm, impede or impair operation of the software or hardware or otherwise cause harm to any software, hardware or data; (v) to the extent Services are purchased from Supplier hereunder, all such Services shall be



performed in a good and workmanlike manner, consistent with all applicable industry standards; (vi) Supplier shall provide all complete and accurate information required for the import and export of the Products and/or Services, including but not limited to certificates of origin, customs information, and export control classifications; (vii) neither Supplier, nor any parent, subsidiary, officer, director, employee, sub-supplier, third party agent or affiliate of Supplier (collectively "Entities") are included on any of the restricted party lists maintained by the U.S. Government or any other governmental or non-governmental entity, including, but not limited to; the SDN List and Foreign Sanctions Evaders list administered by OFAC, Denied Parties List, Unverified List or Entity List maintained by BIS, the Excluded Parties List maintained by the GSA, the List of Excluded Individuals/Entities maintained by the HHS OIG, or the List of Statutorily Debarred Parties maintained by the U.S. State Department's DDTC, or the consolidated list of asset freeze targets designated by the United Nations, European Union, and United Kingdom (collectively, "Restricted Party Lists"); and (viii) any software provided under this PO is not subject to undisclosed licensing restrictions and does not contain open source code. Supplier shall immediately notify MDT if Supplier, or any of its Entities, becomes listed on any Restricted Party List. If the specifications, drawings and other instructions are not attached to the PO, it is the Supplier's responsibility to acquire the required documents, with current revisions, from the MDT representative that issued the PO. Further, Supplier warrants that the Products and/or Services will be free from defects in materials, workmanship and design. The warranties set forth in item (i) above shall not be deemed waived by MDT's acceptance of or payment for the Products and/or Services.

EQUAL OPPORTUNITY; NONDISCRIMINATION. MDT and Supplier shall, to the extent they apply, abide by the requirements of 41 CFR §§ 60-1.4(a), 60-300.5(a) and 60-741.5(a). These regulations prohibit discrimination against qualified individuals based on their status as protected veterans or individuals with disabilities, prohibit discrimination against all individuals based on their race, color, religion, sex, or national origin and require affirmative action to employ and advance in employment individuals without regard to race, color, religion, sex, national origin, protected veteran status or disability. Supplier shall comply with all applicable labor laws, rules, and regulations, including but not limited to, all laws forbidding the solicitation, facilitation, or any other use of slavery or human trafficking. To the extent applicable, MDT incorporates by reference 29 Code of Federal Regulations ("CFR") Part 471, Appendix A to Subpart A, as well as any Federal Acquisition Regulation ("FAR") clauses at 48 CFR Part 52 in effect as of the date of the PO, including but not limited to the E-Verify obligations described in FAR 52.222-54. If Supplier is required by federal Regulations to file Employer Information Report EEO-1 (standard form 100) or Federal Contractor Veterans Employment Report VETS-100A, Supplier certifies that it has done so or will file such reports in accordance with applicable instructions and will continue to file such reports unless or until no longer required by applicable law.

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QUALITY CLAUSES

GENERAL. The following quality clauses apply to all purchases that have the potential to impact the quality of the Product and/or Services provided by MDT or MDT's quality management system. Any conflict between the terms in the PO these Quality Clauses relate to and the Quality Clauses themselves shall be resolved in favor of these Quality Clauses.

MANAGEMENT RESPONSIBILITY. Supplier's management shall provide the resources necessary to implement and maintain a quality management system (QMS), including monitoring of its effectiveness.

SUB-CONTRACTING. Supplier shall not subcontract any of the work subject to this PO without prior written approval by MDT.

REGULATORY SUPPORT. Upon request, Supplier shall provide information necessary for MDT to obtain regulatory approval for the marketing, sale, and distribution of MDT products into which the Supplier's Products or Services are incorporated. Such information may include specific details relating to raw materials, composition, ingredients, etc.



QUALITY MANAGEMENT SYSTEM. Supplier shall, during fulfilment of all accepted POs, maintain a QMS that monitors all aspects of the work performed. QMS shall include, at a minimum: documented procedures as required by the QMS, documents needed by the organization to ensure the effective planning, operation and control of its processes, and records required by the QMS. Monitoring (i.e. internal audits) to ensure compliance with its QMS, procedures, any applicable standards and MDT requirements.

RECORDS. Supplier shall keep complete records that provide evidence of conformity to all requirements of the QMS. Records shall be maintained in a manner that allows them to be readily retrievable and to prevent deterioration, damage or loss. Electronic approval and storage of records is expected to comply with FDA 21 CFR Part 11 requirements. Unless record retention, responsibilities are otherwise agreed with MDT, supplier shall maintain records for 15 years, or a time period as required by applicable laws, rules or regulations, whichever is greater. Records shall be made available for inspection by MDT, its representatives, any relevant regulatory authority such as a Notified Body or FDA, or a government authority.

COMPETENCY AND TRAINING. Supplier shall provide adequate and competent personnel for the fulfilment of the PO.

WORK ENVIRONMENT. Supplier shall maintain an appropriate infrastructure, work environment, and cleanliness of personnel to prevent adverse effects on product or service quality.

CONTROL OF SPECIFICATIONS. Supplier shall control the distribution and use of all specifications and documents pertaining to the PO. To the extent there is a conflict between product specifications provided to Supplier by MDT and the requirements herein, the product specifications shall govern.

IDENTIFICATION AND TRACEABILITY. Supplier shall maintain identification and traceability of raw materials, components and products during all stages of receipt, processing, test, storage, shipment and distribution.

CONFORMANCE TO REQUIREMENTS. Supplier warrants that the Products and/or Services will be free from defects in materials, workmanship and design and are supplied to MDT in accordance with the specifications, drawings and other written instructions provided with this PO. For Services purchased from Supplier, all such Services shall be performed in a good and workmanlike manner, consistent with all applicable industry standards.

CONTROL OF NON-CONFORMANCES. Supplier shall have a process and procedures in place for the control of non-conforming Products or Services at all stages of Supplier's operations, which includes identification, documentation, evaluation, segregation and disposition of the nonconforming product or service conditions. Supplier shall have procedures that govern rework of non-conforming product.

ESCAPES. In the event Supplier discovers a non-conformance that affects Products already shipped or Services performed, Supplier shall promptly notify MDT. Supplier shall fully cooperate with all investigation and containment actions. Supplier shall reimburse all costs and expenses incurred by MDT in connection with use of Nonconforming Product. MDT may return all nonconforming Products to Supplier, at Supplier's expenses.

CAPA. Supplier shall maintain procedures for Corrective and Preventive Action (CAPA). Where a product or service is identified by MDT as nonconforming, MDT may issue a supplier CAPA. Supplier shall complete all necessary CAPA activities within mutually agreed timeframes.

PROCESS CONTROL. Supplier shall control processes that affect product or service quality and performance, including but not limited to: approval of processes and process equipment including qualification and where appropriate, validation, monitoring and control of process parameters, including a documented control plan, if required, and compliance with all specified reference standards. MDT reserves the right to review and approve Supplier's qualification/validation plans and reports.



EQUIPMENT CONTROL, MAINTENANCE AND CALIBRATION. Supplier shall have documented systems in place to ensure process and test equipment is controlled, maintained, and calibrated at stated frequencies, to ensure it is suitable for its intended purpose and is capable of producing valid results. Product potentially impacted by use of out of calibration equipment shall be treated as Nonconforming Product. Calibration standards shall be traceable to recognized national and/or international standards.

CONTROL OF SUB-TIER SUPPLIERS. Supplier shall maintain controls, commensurate with risk, for the quality of all Products and Services procured in connection with the performance of work subject to the PO. Controls must include, as applicable, the flow down of applicable MDT requirements and ensuring action is taken when sub-tier performance is not acceptable.

ACCEPTANCE ACTIVITIES. Supplier shall maintain processes to ensure Products or Services conform to MDT requirements, including as appropriate, incoming, in-process and final acceptance activities. Records of acceptance activities shall be maintained. Records shall include the acceptance activity performed, date performed, the results, the individual conducting the acceptance activity and the equipment used. Where required by MDT, Supplier shall provide a Certificate of Conformance and/or Analysis for each lot or batch of product shipped, or for the service provided.

CHANGE CONTROL. Any process changes, design changes or deviations considered by the Supplier and/or sub-tier must be submitted to MDT for review and must include a detailed description of the change and its effects to the Products and/or Services characteristics.

AUDITS/INSPECTIONS. Supplier agrees that MDT, any government, notified body, commission, board, regulatory agency, court or other instrumentality having any jurisdiction over all aspects of the design, manufacturing and distribution of the Products ("Authority"), shall have access to and the right to inspect or audit any pertinent Product manufacturing or quality processes, and associated documentation or records. The Supplier may specifically be subject to scheduled or unannounced audits (per EU Recommendation 2013/473/EU). During unannounced audits, the Supplier must allow the Authority to witness the testing of Product samples, and/or if requested, provide samples of Product for independent testing by the Authority. If issues or findings are identified during an audit that potentially impact product or service quality, performance or availability, Supplier shall promptly notify MDT and agree to cooperate regarding communications with FDA, regulatory, or government authority.

LABELING, PACKAGING, HANDLING & STORAGE. Supplier shall ensure that packaging and shipping containers are of adequate design and construction to protect product from damage, deterioration or alteration during handling, storage and distribution. Expiration dates and any required storage conditions shall be clearly recorded on the labelling, packaging and shipping documents. Supplier shall create and store labels and perform labelling operations in a way that prevents an incorrect label from being used.

SHIPMENT. Supplier shall have systems in place to control shipment of Products so that only Products approved for release are shipped. Supplier shall ensure that no obsolete, rejected, expired or deteriorated Products are shipped.

COMPLAINTS. Supplier shall provide assistance and information requested by MDT in relation to the investigation of complaints MDT receives from its customers, and to fulfil its regulatory reporting obligations. Where the complaint is confirmed to be attributed to the product or service provided, Supplier shall follow the CAPA process.

RESTRICTED SUBSTANCES/MATERIAL DECLARATION. Products and Services supplied to MDT are expected to meet all applicable requirements of country, federal, state and local environmental regulations. Suppliers of packaging, components and finished devices (Products) are expected to provide information about the specific composition (e.g. trade or chemical name, color, grade, etc.), including quantity of all constituents used in the Products and packaging and/or provide



specific certifications to MDT upon request. This detailed information, declaring the raw materials and process chemicals used to manufacture the Products and packaging is required to fulfill Regulatory Body requirements for approval for use and other environmental reporting obligations.

RECALLS. Supplier shall promptly notify MDT in writing in the event Products or Services provided become subject to a supplier or Authority initiated recall and shall cooperate with MDT requests for information related to the recall. MDT has the sole authority for decisions related to any of its products in the field, including any field corrective action.

SURVIVAL. All quality requirements which are continuing in nature, including but not limited to CAPA, nonconforming product, escapes, authority audits & inspections, record retention, complaints, recalls, shall survive termination or cancellation of the PO.

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