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 Medtronic ("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 or equivalent. 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 in these Quality Clauses, the MDT 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 established specifications, drawings and any 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 NONCONFORMANCES. Supplier shall have a process and procedures in place for the control of nonconforming 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 specified or approved allowed rework of nonconforming product.

ESCAPES. In the event supplier discovers a nonconformance that affects products already shipped or services performed, supplier shall promptly notify MDT. Supplier shall fully cooperate with all investigation and containment actions.

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 at **changerequest.medtronic.com** 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.

CONFIDENTIALITY: Suppliers shall keep confidential all non-public information received from or created by Medtronic. Supplier shall disclose to Medtronic in a timely manner any compromises in the Supplier's security that could impact Medtronic product, data, or Product Related Software.

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. Supplier acknowledges that Medtronic has certain legal, regulatory, environmental, and contractual reporting obligations and suppliers of packaging, components and finished devices (products) agree to provide MDT with 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. Supplier further agrees that latex gloves shall not be used at any point during the manufacturing process.

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.