minimed

Supplier quality excellence playbook

Creating a predictable supply through unwavering commitment to quality

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An important building block for a successful Supplier-Customer partnership is communication. The playbook provides an overview of MiniMed's expectations to its Suppliers. Its purpose is to give our Suppliers and potential Suppliers the information required for securing business and maintaining a successful partnership.

Introduction 1.0

1.1 How to use this playbook

The first three sections of this document provide an overview of MiniMed, the key roles in the sourcing organization, and an overview of MiniMed's expectations. The remaining sections provide more detailed expectations.

The playbook aligns with the content of ISO13485 Medical Devices – Quality Management Systems – Requirements for Regulatory Purposes; however, it is not intended to take the place of the standard itself.

We recognize that MiniMed has a wide variety of Suppliers and technologies; the expectations stated in this playbook may apply in different ways, depending on the Product or Service supplied.

Terms and definitions used in this Playbook are listed in Appendix B.

MiniMed welcomes any questions regarding the content of the Supplier Quality Excellence Playbook.

1.2 Purpose and scope

The purpose of this Supplier Quality Excellence playbook is to clearly communicate MiniMed's Quality expectations to all new and existing external Suppliers. These Quality expectations apply to the development, manufacture, and delivery of all Products and Services supplied to MiniMed. Suppliers have a direct impact to MiniMed delivering high-quality Product to our customers. Therefore, it is important to understand expectations, identify gaps and track progress to gap resolution. MiniMed establishes long-term partnerships with Suppliers who strive to meet performance expectations and comply with regulatory requirements.

Quality requirements and expectations may take the form of an agreement or Specification. The expectations and guidance within this Playbook are provided as a supplement, not as a replacement for or altering of the terms or conditions with pre- established agreements, engineering drawings or Specifications.

If conflicting interpretations of the standards arise, the following order of precedence applies unless otherwise noted contractually:

1. Agreements (Quality, Supply, etc.)
2. Specification Requirements
3. MiniMed Purchase Orders
4. Supplier Quality Excellence Playbook

1.3 Code of conduct

Our relationships with Suppliers are based on lawful, efficient, and fair practices. MiniMed expects our Suppliers and contractors to:

- Abide by applicable laws, rules and regulations of the countries in which they operate
- Uphold the human rights of workers and treat them with dignity and respect
- Ensure a safe and healthy working environment
- Practice social and environmental responsibility
- Demonstrate the highest standards of business ethics
- MiniMed reserves the right to discontinue business relationships with Suppliers that fail to conduct business in a legal, responsible, and ethical manner.

Appendix C contains a list of regulations and standards that are applicable to MiniMed and may be applicable to our Suppliers also.

1.4 MiniMed mission

The MiniMed mission is very important to us as a company. First and foremost, our mission is **to make is to make every day a better day for people with diabetes.** We at MiniMed are committed to fulfilling this mission and expect the same commitment from our Suppliers.

1.5 Our products

Our various key technologies develop, manufacture and market-advance integrated diabetes management solutions. These technologies include:

Insulin Pump Systems

- Advanced insulin pump therapy devices that deliver precise insulin doses throughout the day
- Feature programmable basal rates, bolus calculators, and customizable settings
- Designed for continuous subcutaneous insulin infusion (CSII)

Continuous Glucose Monitoring (CGM) Systems

- Real-time glucose sensors that monitor glucose levels continuously
- Provide alerts for high and low glucose levels
- Transmit data wirelessly to pumps or display devices

Integrated/Hybrid Closed-Loop Systems

- Advanced automated insulin delivery systems
- Combine insulin pump and CGM technology
- Use algorithms to automatically adjust insulin delivery based on glucose readings
- Sometimes referred to as "artificial pancreas" technology

Infusion Sets and Sensors

- Disposable components for insulin delivery and glucose monitoring
- Various types to accommodate different patient preferences and needs
- Include insertion devices for easier application

For more information go to www.minimed.com

1.6 Environmental/ social obligations

We hold our Suppliers to the same high standards of business conduct and social and environmental responsibility. We expect our Suppliers to:

- Comply with the laws, rules, and regulations of the countries in which they operate
- Uphold the human rights of their workers and
- Labor Standards Policies
- Ensure a safe and healthy workplace
- Practice social and environmental responsibility
- Demonstrate the highest standards of business ethics

As Suppliers deliver goods or services to MiniMed, they are certifying their compliance to all of the above points. We reserve the right to evaluate, audit, and inspect Suppliers' facilities, operations, and records at any time to make sure they are in compliance. MiniMed reserves the right to take appropriate Supplier action up to termination of the business relationship as a result of a violation.

1.6.1 Conflict minerals

MiniMed expects Supplier to comply with the U.S. Securities and Exchange Commission (SEC) rules for reporting and disclosure requirements related to Conflict Minerals as part of the Dodd-Frank Wall Street Reform and Consumer Protection Act of 2010 ("Dodd-Frank Act"). MiniMed supports the goals and objectives of Section 1502 of the Dodd-Frank Act that requires public companies to determine the sourcing of tin, tungsten, tantalum, and gold used in their Products and to file an annual report disclosing any such use.

1.6.2 World customs organization trade security program

To ensure the security of MiniMed's global supply chain, MiniMed expects Suppliers who export items to MiniMed to:

(i) obtain World Customs Organization (WCO) Authorized Economic Operator (AEO) Trade Security Program certification i.e.. Customs Trade Partnership Against Terrorism (C-TPAT) and provide evidence of such certification to MiniMed; or (ii) demonstrate to MiniMed that it meets the criteria for such certification and has policies and procedures in place that meet WCO AEO Trade Security Program requirements and enable MiniMed to audit/monitor compliance with WCO and AEO standards/trade security criteria; or (iii)) engage a third- party logistics provider and freight forwarder that maintain membership in such trade security program and certify that they will only use these entities for exports to MiniMed sites.

MiniMed expects Supplier to comply with the U.S. Securities and Exchange Commission (SEC) rules for reporting and disclosure requirements related to Conflict Minerals as part of the Dodd-Frank Wall Street Reform and Consumer Protection Act of 2010 ("Dodd-Frank Act"). MiniMed supports the goals and objectives of Section 1502 of the Dodd-Frank Act that requires public companies to determine the sourcing of tin, tungsten, tantalum, and gold used in their Products and to file an annual report disclosing any such use. As part of our commitment to responsible sourcing and human welfare, MiniMed and our Supplier are expected to adopt a Conflict Minerals Policy.

1.7 Continuous improvement

MiniMed strives for reliability and quality in all of our Products. MiniMed recognizes that this cannot be done without the support of a strong supply base. To that end, MiniMed strives to achieve a world-class supply chain utilizing Lean Sigma methodologies that address the waste and variability in processes and supply chain systems. Lean Sigma combines Six Sigma with Lean Manufacturing methodologies.

MiniMed is dedicated to aligning its continuous improvement strategies with its supply base, namely through the, Supplier Owned Quality.

1.7.1 Supplier development

The Supplier Development program engages Suppliers to continuously improve process capability, reduce waste and variability, and other activities and projects. It utilizes tools such as Lean Six Sigma, Kaizen, Rapid Improvement Events, Value Stream Mapping, First Time Quality (FTQ) events, and training to perform gap analyses, reduce lead times and reduce defects. MiniMed trained engineers will partner with strategic Suppliers to drive process improvements throughout the value stream that they share.

Both MiniMed and our Suppliers can benefit from Supplier Development in the following ways:

- Improved quality and yield
- Supplier Owned Quality (SOQ)
- Improved production throughput
- Improved customer responsiveness (on-time delivery; lead time reduction)
- Cost reductions (inventory, overtime, labor and burden)
- Growth with less capital investment
- Opportunity to become a MiniMed Supplier Owned Quality participant

To achieve these mutual benefits, MiniMed partners with Suppliers on specific projects to implement process improvements that have positive outcomes for current and future Products.

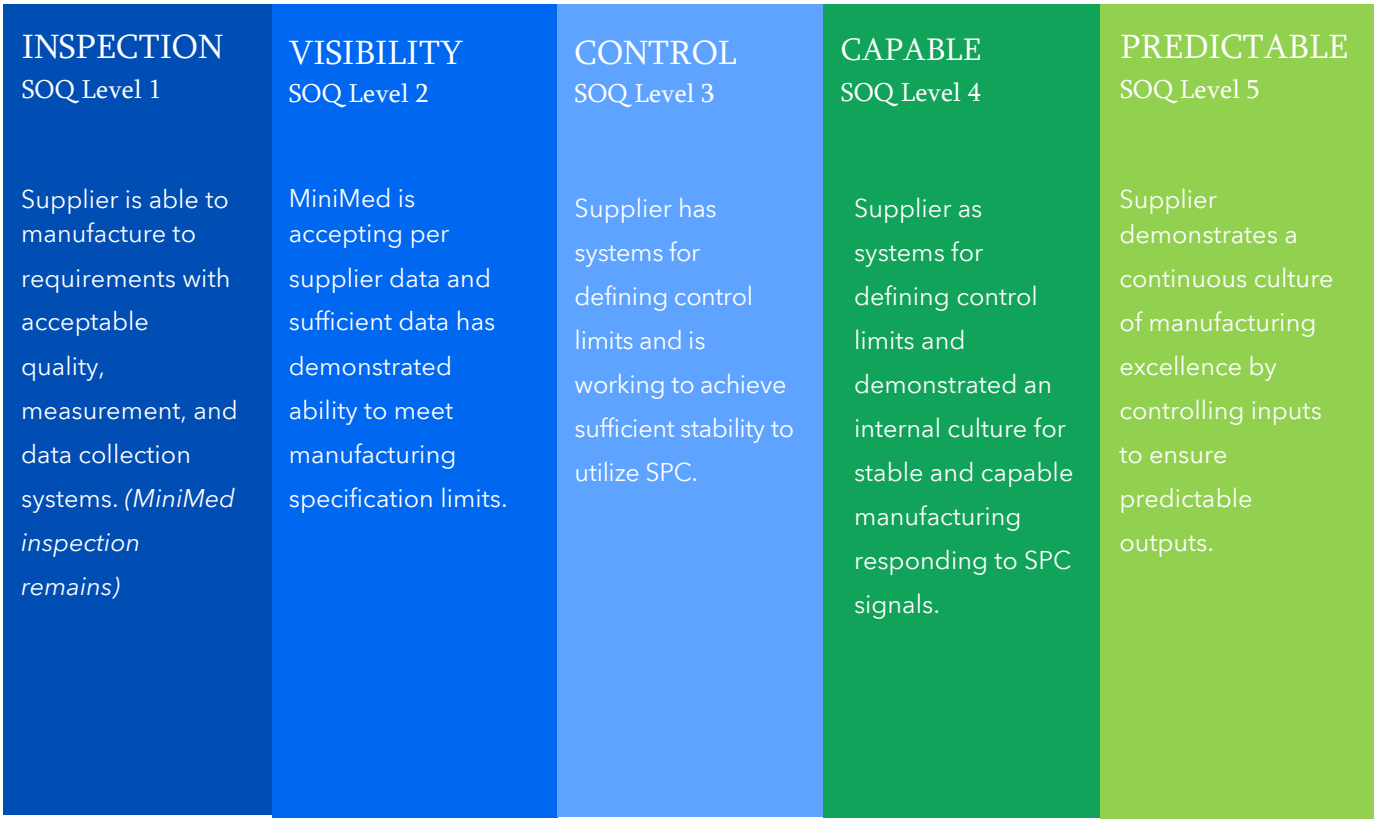
1.7.2 Supplier owned quality

Supplier Owned Quality (SOQ) is a program developed to support the Supplier owning the Product quality of Products they deliver. Its aim is to avoid duplication or repeat inspection efforts within MiniMed. While MiniMed continues to own overall quality of our Product, our Suppliers are expected to own Product quality in all the Product and Services (including their processes) that they provide. SOQ links the Supplier's Product inspection data results to MiniMed, streamlining the acceptance process.

Select Suppliers benefit from engaging in SOQ initiative by challenging themselves to meet increasing levels of supply maturity to ensure stable and predictable Products. The SOQ program has various maturity levels. Both the Supplier and MiniMed can monitor and act on performance trends to support improved Product outcomes.

Suppliers benefit from SOQ by receiving early feedback regarding MiniMed's Product acceptance thus mitigating the risk of Product returns and the need to hold excessive inventory to support long acceptance lead times. Achieving the highest maturity levels with Statistical Process Control (SPC) reduces manufacturing variability and lowers scrap costs.

Figure 1: Maturity Model of SOQ



Key roles and responsibilities

2.0

2.1 MiniMed supply management

The Supply Management representative serves as the supplier's primary contact, responsible for ensuring streamlined communications, facilitating access across multiple functional areas, and managing the overall supplier relationship. This includes supplier onboarding, contractual relationships, quality standards, cost management, delivery performance, and comprehensive understanding of any supplier-related risks to the organization.

2.2 Supplier organization

MiniMed expects our Supplies to identify a designated contact within their organization to communicate with MiniMed for each function below:

2.2.1 Customer representative

The customer representative is the primary contact within the Supplier's organization for any key communications with MiniMed, including any quality, delivery, or commercial issue resolution.

2.2.2 Quality management representative

The Quality Management Representative within the Supplier's organization is responsible for the implementation and maintenance of the Supplier's Quality Management System such as defined by ISO 9001 and/or the ISO 13485 series of standards.

Overview of supplier expectations

3.0

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

3.1 Quality agreements

In addition to the expectations contained in this Playbook, MiniMed will determine if a Quality Agreement is needed with our Suppliers.

Quality Agreements outline the Supplier specific quality requirements and may be in the form of a stand-alone Quality Agreement or as part of the Purchase Order and / or material Specification. Once the need is determined, it is expected that the Supplier will work with MiniMed to put this agreement in place.

3.2 Non-disclosure agreements

Suppliers may be asked to sign a non-disclosure agreement, depending on the level of technology or information disclosed during the course of business. It is our policy to utilize a MiniMed standard form that has been created for this purpose.

Information provided to Suppliers involving various trade secrets, designs, materials and other proprietary information of a secret and confidential nature may include, but are not limited to records, data, schedules, forecasts, formulae, processes, procedures, Specifications, developments, designs, inventions, models, techniques, improvements or discoveries, patentable and otherwise.

It is MiniMed's policy that Suppliers shall not use, transmit or disclose confidential information to any third party except in accordance with the terms of the non-disclosure or any other written agreement. Supplier shall not make any public announcement about or advertise the existence of this Agreement, divulge its terms and conditions or any relationship with MiniMed other than with prior written agreement of the other party. Suppliers shall agree not to display or use the MiniMed logo, trade secrets, trademark, or Product(s) in any manner without prior written permission from their MiniMed Supply Chain Representative.

MiniMed values our relationships with our Suppliers and aims to protect them through the use of this formal agreement.

3.3 Environmental compliance

Products & Services supplied to MiniMed are expected to meet the requirements of country, federal, state and local environmental regulations. The list below includes some of the regulations; however, compliance is not limited to these. Additional information may be required such as certification to any of the following or chemical composition of Products to determine compliance to regulations and customer requirements. Any suspicions that Products supplied to MiniMed are not compliant, are expected to be communicated to the appropriate buyer or supply chain representative immediately.

- CA Prop 65: California Office of Environmental Health Hazard Assessment Proposition 65
- China RoHS: Decree 591 SJ/T 11364-2014
- EU Battery Directive 2006/66/EC and amendments
- EU MDR: European Union Medical Device Regulation 2017/745 (Annex 1, Chapter II, §10.4.1)
- EU Packaging Directive 94/62/EC and amendments
- Health Canada: Canada – SOR/2014-254
- EU POPs: EU Persistent Organic Pollutants, EC Regulations No. 850/2004, No. 757/2010 and No. 2019/1021 and related amendments, including restriction of perfluorooctanoic acid (PFOA), its salts and PFOA-related substances to 25 ppb (0.0000025 % by weight)
- REACH: Registration, Evaluation, Authorization, and Restriction of Chemicals EU 1907/2006
- RoHS 2&3: Restriction of Hazardous Substances Directive 2011/65/EU & Amendment 2015/863
- EU WEEE: EU Waste Electrical and Electronic Equipment Directive 2012/19/EU
- Latex: Natural Rubber Latex FDA 21 CFR 801.437
- Animal Derived Materials, e.g., ISO 22442, EU 722/2012
- Hydrochlorofluorocarbons FDA 40 CFR 82.100 – 82.124
- Nanomaterial

3.4 Declaration of raw materials used

Supplier Products and Services supplied to MiniMed shall meet all applicable Environmental Regulation requirements regarding product and packaging content. Suppliers of products are expected to have product content information about the specific composition ((e.g., trade or chemical name, CAS number, color, grade, etc.), including, but not limited to, quantity and/or concentration of all constituents; process residuals and other chemicals used in the Products and packaging manufacture (Product and Packaging Content) and/or provide specific certifications to MiniMed upon request regarding such product and packaging content. This product and packaging content certification is required to comply with Environmental Regulation requirements for approval for use and other environmental reporting obligations.

3.5 Trade compliance

As Business becomes increasingly globalized, additional documentation and processes are required. Suppliers who ship Product across international borders to a MiniMed facility need to be aware of the following:

- MiniMed requires suppliers to follow all applicable laws and regulations for exporting items to MiniMed facilities. This includes processes for the classification of items for export (Export Control Classification Number ECCN or ECN), obtaining all required export authorizations, and ensuring the supplier is not engaging in transactions with restricted parties or sanctioned countries.
- MiniMed requires that, unless exempted by law, every material sales packaging label, outer carton label, and finished device, where possible, must include an accurate country of origin for customs purposes in a conspicuous place as legibly and permanently as possible to indicate the English name of the country of origin, unless other language is required by local law.
- A commercial invoice signed by the seller, shipper or associated agent is required for Customs entry and is expected to be prepared in accordance with the customs regulations and requirements of the country of import. Any inaccurate or misleading statement of fact in the commercial document may result in delays in release, detention of goods, increased chance of inspection by import officials or penalties against the importer.
- In order to significantly reduce the introduction and spread of pests via the movement of goods across international borders to MiniMed facilities, wood packaging material is closely regulated. MiniMed Suppliers must comply with the International Plant Protection Convention's (IPPC) International Standards for Phytosanitary Measures No. 15 (ISPM 15) which requires wood packaging material to be either heat treated or fumigated with methyl bromide and stamped or branded with the IPPC mark of compliance.

3.6 Business continuity

MiniMed expects our Suppliers to complete a formal business Disaster Recovery Plan to ensure no interruption in supply to our patients is encountered. While contingency plans cannot be expected to cover all potential scenarios, we expect our Suppliers to maintain robust plans to facilitate rapid response and recovery in the event of disruptions.

MiniMed expects its Suppliers to have a comprehensive crisis management approach to deal with potential disruptions. The approach is expected to include a plan of action, communication plans, escalation procedures, and roles and responsibilities. This plan is expected to address the recovery time needed for a variety of business interruptions, contact information for key locations, supply chain assessment of risk for equipment, material, supplied Components and labor, etc. and be specific to MiniMed Products and/or Services provided.

3.7 Change management

Change control is an essential element of ensuring we maintain the quality of our Products. We recognize that continuous improvement efforts may require changes to manage cost, quality, delivery and technology.

Through communication and collaboration, we can ensure that these changes do not have unintended effects on our Products and therapies, our operations and, more importantly, our customers and patients. Suppliers are responsible for notifying MiniMed of changes made to materials, Products or processes, including changes at sub-tier Suppliers.

Suppliers are expected to notify MiniMed prior to implementing any change by submitting a request through the Supplier Change Request (SCR) system at link below:
changerequest.medtronic.com

Note: Approval from MiniMed is required prior to implementing any changes. See section 7.2.3 for additional detail.

3.8 Sub-tier supplier control

Suppliers are expected to manage sub-tier Suppliers with controls commensurate with risk. Suppliers are responsible to ensure that Product(s) manufactured utilize only authentic, conforming and specified material as stipulated in the Specification.

MiniMed's expectation is that the Supplier has in place formal Purchasing and Supplier control processes to manage sub- tiers. These controls are expected to include:

- Selection, evaluation and approval
- Product qualification
- Procurement
- Product acceptance
- Performance measurement and monitoring, including sub tier auditing programs
- Nonconforming Product and CAPA processes
- Change control

Suppliers are responsible for ensuring and controlling the quality of all Components and raw materials that are purchased to manufacture Product for MiniMed.

Where MiniMed requires a Supplier to engage with a specified sub-tier Supplier, relationship management will be established between MiniMed and the Supplier. Note: Prior to

implementing sub-tier Supplier changes, Suppliers are expected to seek MiniMed approval (see section 7.2.3 for additional details).

3.9 Measurement system analysis (MSA)

MiniMed expects Suppliers to develop and maintain capable, accurate and stable measurement methods and systems.
Measurement System Analysis (MSA) is recommended in determining whether measurement or test equipment has sufficient accuracy, precision, or resolution to adequately provide information about process performance, or the effects of inherent or applied variation of the process under development. One recommended tool is Gage Repeatability and Reproducibility (Gage R&R or GR&R).

3.10 Process capability

MiniMed expects Suppliers to develop and maintain highly capable processes to produce quality Products and Services. Indicated features will be defined in MiniMed Specifications when applicable.

3.11 Control plans

Each MiniMed business entity or region uses risk assessment to identify the need for Control Plans for purchased Products.
A Control Plan is a documented description of the systems for controlling part and process quality by addressing indicated features and engineering requirements. Each Control Plan describes the actions that are required at each phase of the process including receiving, in-process, outgoing, and periodic requirements. Control Plan methodology is expected to be fully integrated into the Supplier's QMS. A Supplier's Control Plan template may be used in lieu of MiniMed Control Plan template as long as the content reflects the requirements as defined by MiniMed to ensure ongoing process control.

3.12 Cost of poor quality (COPQ)

MiniMed shall notify Suppliers of Nonconforming Product. MiniMed expects Suppliers to replace nonconforming materials free of charge. Suppliers are expected to cover expenses (including freight and customs clearance, if any) incurred by MiniMed in connection with (a) shipment of replacement Product to the same location and (b) shipment of the Nonconforming Product back to Supplier (if so requested by Supplier). In the event of a rejection of Nonconforming Product, Suppliers are expected to ship replacement Product as soon as practical.

Quality management system

4.0

The Supplier's management is expected to establish, document, and implement an effective Quality Management System (QMS).

4.1 Expectations

Suppliers that provide Finished Medical Devices are expected to have a QMS in place that complies with the requirements of ISO9001, ISO13485, FDA 21 CFR Part 820 and/or other comparable standards or regulations. Suppliers that provide Finished Medical Devices are also expected to complete FDA establishment registration and device listing requirements per FDA 21 CFR Part 807 as applicable. All other Suppliers are expected to have a QMS in place that is aligned with or similar to ISO9001, ISO13485, FDA 21 CFR Part 820 or other comparable standard or regulation.

For existing Suppliers that are not certified to ISO13485, it is preferred that those Suppliers have a plan in place to become certified and can demonstrate progress toward that plan. Any changes to the certifications or registrations status are expected to be communicated to MiniMed in a timely manner.

The Supplier is expected to notify MiniMed of a Regulatory inspection. The Supplier is expected to also provide timely notification to MiniMed if it receives a 483, warning letter or finding from a Regulatory Agency.

New Quality System certification is expected to be provided where there are mergers, acquisitions, or affiliations associated with Suppliers. Suppliers are expected to forward evidence of their Quality System certification to MiniMed upon request.

4.2 Documentation

4.2.1 General

The Quality Management System documentation is expected to include, at a minimum:

- Documented statements of a quality policy and quality objectives
- Documented procedures as required by the Quality Management System
- Documents needed by the organization to ensure the effective planning, operation and control of its processes
- Records required by the Quality Management System

4.2.2 Control of Documents

Suppliers are expected to establish, maintain, and document procedures to control all Quality Management System documentation and all data generated under the Quality Management System. Suppliers are expected to have a documented procedure for the control and distribution of drawings, documents and/or standards. Obsolete documents are expected to be destroyed or appropriately identified as such for limited distribution.

4.2.3 Control of Records

Records are expected to be stored in an environment that will prevent deterioration, damage, or loss, and are expected to be readily accessible to MiniMed upon request. Suppliers will make available any and all quality Records, in a timely manner, upon request by MiniMed or any regulatory body such as the FDA. Electronic record approvals and storage are expected to comply with 21 CFR Part 11 requirements. All quality Records are expected to be retained for a period of time equivalent to the design and expected life of the device.

4.3 Complaints and adverse events reporting

MiniMed has the sole authority to correspond with all applicable regulatory authorities with respect to complaints about the Product(s). MiniMed is responsible for complying with all regulatory requirements pertaining to the reporting of adverse events.

Specific requirements are defined in Quality Agreements, but in general Suppliers are expected to cooperate in dealing with customer and third party complaints and adverse events concerning the Product(s) and are expected to take action to promptly resolve such complaints and adverse events. Suppliers are expected to:

- Give prompt notice to MiniMed by email or by telephone as soon as becoming aware of a Product complaint or adverse event and provide written follow-up to MiniMed.
- Maintain a written Record of all customer and third-party complaints and adverse events that relate to the Product(s), whether received orally or in writing;
- Establish a tracking and traceability system for all Product(s) so as to permit successful tracking in the event of a Recall.
- Maintain complaint and adverse event Records and files in accordance with Quality System requirements.

4.4 Field corrective actions

If either party, in good faith, determines that a field corrective action or other action (e.g. Product Hold Order) involving a Product(s) should be considered, it will immediately notify the other party. MiniMed will have the sole authority to determine whether any action such as a field corrective action or other action shall be undertaken where it owns the design and regulatory approval. Suppliers are expected to cooperate with MiniMed to implement the action once the determination is made.

Management responsibilities 5.0

Supplier's senior management is expected to ensure an effective and continuously improving Quality System and maintain an organizational structure which ensures the Product is designed, developed and manufactured to MiniMed requirements.

Senior management is expected to ensure that appropriate communication is established with MiniMed regarding the effectiveness of and any changes in the Supplier's Quality Management System.

5.1 Management commitment

The Supplier's senior management is expected to demonstrate a commitment to continuous improvement. Senior management is expected to provide documented evidence of its commitment to the development and improvement of the Quality Management System by:

- Communicating to the organization the importance of meeting customer as well as regulatory expectations and requirements
- Establishing the quality policy and objectives
- Conducting regularly scheduled management reviews on the effectiveness of the quality system and taking appropriate action when indicators are unfavorable
- Ensuring the availability of necessary resources

5.2 Customer focus

The Supplier's senior management is expected to ensure that customer needs and expectations are identified, converted into requirements, and fulfilled with the aim of achieving customer satisfaction. MiniMed expects that Suppliers conform to design and performance Specifications. Suppliers are expected to meet requirements for reliability, delivery, cost management, and technical support.

5.3 Quality policy

The Supplier's Senior management is expected to endorse a written quality policy that:

- Is appropriate to the purpose of the organization
- Includes a commitment to meeting customer requirements and to continuous improvement
- Provides a framework for establishing and reviewing quality objectives
- Is communicated and understood at all levels in the organization
- Is reviewed for continued appropriateness

5.4 Quality planning

The Supplier's senior management is expected to ensure that goals and objectives are established for the appropriate functions and levels. The goals and objectives are expected to be measurable and consistent with the Supplier's quality policy.

5.5 Responsibility, authority and communication

5.5.1 Responsibility and Authority

A Quality Management System is expected to be implemented in order to provide confidence that the organization can satisfy the needs of its customers. The system is expected to be consistent with the Supplier's size, culture, and Products. Suppliers are expected to show evidence of a quality policy emphasizing continuous quality improvement driven by senior management. Management is expected to define specific quality indicators and goals, as well as have a system in place to track and monitor trends. Improvement activities are expected to be based around these trends.

5.5.2 Management Representative

The Supplier's senior management is expected to appoint member(s) of management who have responsibility and authority for the planning, execution, control, and improvement of quality-related activities.

5.5.3 Internal Communication

The organization is expected to ensure that communication takes place at all levels and to all functions regarding compliance to the Quality Management System and its effectiveness.

5.6 Management review

The Supplier's management is expected to evaluate the degree of compliance and effectiveness of the Quality Management System. Management Reviews will be held at set intervals with a pre-determined agenda that includes review of performance metrics and corrective action(s). A formal corrective action process is expected to address deficiencies within the Quality Management System. Action items are expected to be assigned and recorded in the minutes with follow-up in adjacent Management Reviews.

Resource management

6.0

Suppliers are expected to provide the resources necessary to implement and maintain an effective Quality Management System and to continually improve its effectiveness. Employees of the Supplier are expected to be qualified for the job they perform through education, training, and/or work experience, and be knowledgeable of appropriate quality tools, defect awareness, and processes that affect the quality of Products and Services provided to MiniMed. Suppliers are expected to maintain evidence of required and completed training. Suppliers are expected to maintain an appropriate work environment to prevent adverse effects on Product quality.

Product realization

7.0

7.1 Planning of product realization

Suppliers are expected to evaluate and meet requirements for the Product or Service provided including:

- Quality Requirements specified by MiniMed.
- Statutory and regulatory requirements related to the Product.
- Supplier's own Specifications and Quality Playbook requirements.

Before committing to supply Product to MiniMed, the Supplier is expected to hold a Contract Review of the requirements related to the Product or Service, stated above, to ensure that Product or Service requirements are defined, order requirements are understood, and the Supplier has the ability to meet the defined requirements.

7.2 Customer expectations

7.2.1 Design for reliability and manufacturability (DRM)

DRM is a program for achieving Product excellence through application of Lean Sigma practices, methods and tools to improve Product performance, reliability, manufacturability and costs. It is essential that we work together to understand requirements, apply design for manufacturability principles, and develop robust processes where capabilities are understood and effectively controlled. DRM elements include:

- Strategic Technology Planning
- Voice of the Customer (VOC)
- Concept Engineering
- Requirements Flow Down
- Robust Design
- Use Conditions
- Design for Manufacturing & Assembly (DFMA)
- Design for Reliability (DFR)
- Capability
- Control

7.2.2 Communication to MiniMed

Suppliers are expected to identify and implement a communication plan with MiniMed regarding Product information, contracts, order handling, and customer feedback and complaints. Suppliers are expected to provide prompt notification to MiniMed of any Supplier Product recalls.

Suppliers are expected to provide MiniMed the documents, paper or electronically, required to determine acceptance of Product during inspection, e.g. Certificate of Conformance, Certificate of Compliance, etc.

7.2.3 Supplier's obligations for timely and proper notification of change

7.2.3.1 Changes by MiniMed

The Specifications may be revised by MiniMed. Such revisions may require additional qualification. MiniMed will notify Supplier of all relevant Specification revisions. The Supplier is expected to implement all revisions by agreed upon dates.

7.2.3.2 Changes by Supplier

Any process changes, design changes or deviations considered by the Supplier and/or sub-tier must be submitted to MiniMed for review at **changerequest.medtronic.com** to allow MiniMed time to qualify and approve the change(s) prior to implementation. Supplier must include a detailed description of the change and its effects to the products and/or services characteristics. Supplier shall not implement change(s) impacting a MiniMed Site/Business Entity prior to the specific MiniMed Site/Business Entity approval of the submitted change request, if applicable. Suppliers are expected to have a process to identify and manage changes from their Suppliers in a timely manner. It is in both the Supplier's and MiniMed's interest to review any potential changes as early in the process as possible.

7.2.3.3 Change/Approval

MiniMed personnel shall review and approve changes that may affect the Product(s), including, without limitation:

- Altering environment specs or conditions in areas used for Manufacturing, storage, or test (i.e. microbial/endotoxin/particulate monitor)
- New or alternate Sub-Tier Suppliers
- Change at a Sub-Tier Supplier
- Change from playbook to automated process
- Control Plan changes or outgoing inspection plan changes
- Changes to, or deviations from, Validated sterilization parameters or sterilant
- Equipment Qualification or Validation changes
- New equipment
- Process deviation
- Process changes
- Product design changes
- Product test changes
- Product labeling or packaging changes
- Product part number changes
- Supplier Manufacturing site transfers, shutdowns or additions
- Supplier name or address changes
- Raw Materials and/or Component changes, including material composition changes
- Specification changes (e.g. process, Component, Product, test)
- Any changes to use of materials of animal origin
- Products dispositioned as Use As Is by supplier "Use As Is" disposition

7.3 Design and development

When responsible for Product Design, the Supplier is expected to establish and maintain design controls in accordance with ISO13485. Design Control elements include:

- ☐ Design and Development Planning
- ☐ Design Inputs
- ☐ Design Outputs
- ☐ Design Review
- ☐ Design Verification
- ☐ Design Validation
- ☐ Design Transfer
- ☐ Design Changes
- ☐ Control of Design and Development Changes
- ☐ Design History File (Applicable to Finished Medical Device)

7.4 Purchasing

Suppliers are expected to establish and maintain controls on the purchase of Product or Services used in the manufacture of Product to ensure conformance to specified requirements. Purchasing Controls include evaluation and selection of Suppliers to pre-determined criteria, verification of purchased Products or Services, monitoring of Supplier performance (including CAPA) change control and documentation requirements.

MiniMed may choose to evaluate the Supplier's sources to ensure the purchased Product or Service meets specified purchase agreements. In the event that, with MiniMed's knowledge and approval, Supplier subcontracts a portion of the manufacture and/or inspection of Products to sub-tier Suppliers, the expectations described in this playbook are expected to be passed on to those Suppliers. Suppliers are expected to remain responsible for all acts or omissions of their sub-tier Suppliers.

7.5 Identification and traceability

7.5.1 Identification and traceability

Suppliers are expected to establish and maintain a process for identifying and tracking Product during all stages of receipt, internal processing, test, storage, distribution, and shipment. Traceability to the lot / batch level is expected for but not limited to the following:

- Materials
- Process information
- Shipments

7.5.2 Handling, storage, distribution, and installation

Suppliers are expected to have systems in place to ensure that damage, deterioration, contamination or other adverse effects do not occur during the handling, storage and distribution of Product(s).

When a Product requires installation, Suppliers are expected to have adequate installation, inspection and testing instructions.

Control of monitoring and measuring devices

8.0

A Supplier is expected to establish and maintain documented procedures for the calibration, control, and maintenance of measuring, inspection, and test equipment used to ensure that Products and processes conform to applicable requirements. A Supplier is expected to calibrate these devices at consistent periodic intervals against applicable standards traceable to recognized national and/or international standards. If a Supplier finds that a gauge is not calibrated correctly or a gauge with expired calibration was used to verify parts for MiniMed, the Supplier is expected to notify MiniMed.

Measurement, analysis, and improvement

9.0

9.1 General

Suppliers are expected to use measurement, analysis, and improvement of performance metrics for Products delivered to MiniMed. These performance metrics determine the current level of performance, drive continuous improvement activities, and monitor performance levels. Statistical tools are expected to be applied to measure the performance metrics for processes and Products and also supply chain performance. Suppliers are expected to define, plan, and implement measurements where processes affect the quality of Products or Services that MiniMed receives.

9.2 Production and process control

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

- Approved and documented production processes, instructions, and methods that define and control the manner of production.
- Monitoring and control of process parameters and Product characteristics during production.
- Compliance with specified reference standards or codes.
- Approval of processes and process equipment.
- Criteria for workmanship

Suppliers are expected to validate processes used for the manufacture of any Product that cannot be fully verified by subsequent inspection and test (e.g. Sterilization), at a minimum (examples of Regulatory requirements can be found in ISO 13485. Guidance to performance process validation can be found in the publication 'GHTF/ SG3/N99-10, Quality Management System – Process Validation Guidance'. MiniMed would expect to review and approve validation plans and reports.

Suppliers are expected to identify, document and control key manufacturing process steps that affect Product performance.

9.3 Audits & inspections

MiniMed may choose to audit the Supplier's manufacturing and Quality Systems. To ensure compliance to Quality Requirements, MiniMed is expected to have access to observe and inspect Supplier's:

- Facility
- Quality System
- Processes

Suppliers are expected to provide a written response for all MiniMed audit findings in a timely manner. Suppliers are expected to provide access to Regulatory Authorities for inspections or audit. Suppliers are expected to conduct internal audits to ensure compliance with its Quality System.

9.3.1 Unannounced audits (UAA)

FDA, Notified Bodies and other Authorities, which ensure the safety of medical devices shall have access to and the right to conduct unannounced audits of medical device manufacturers including audit any pertinent Product design, manufacturing, or quality process, and associated documentation or Records, Unannounced audits by a Notified Body (NB) may also be performed at MiniMed's critical Contract Manufacturers or crucial Suppliers.

9.4 Monitoring and measurement

9.4.1 Incoming acceptance

Suppliers are expected to have procedures for acceptance of incoming Product, including inspection, testing, and verification as conforming to MiniMed Specifications. Suppliers are expected to document acceptance or rejection of incoming Product.

9.4.2 In-Process acceptance

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

9.4.3 Final acceptance

Suppliers are expected to have procedures for final Product acceptance to ensure that each production unit, lot, or batch of finished Product meets MiniMed's acceptance criteria. Finished Product shall be adequately controlled until released.

9.5 Control of nonconforming product

Suppliers are expected to establish and maintain procedures to control Product that does not conform to MiniMed Specifications. The procedures shall address the identification, documentation, evaluation, segregation, and disposition of Nonconforming Product, including the need for an investigation, which shall be documented.

9.5.1 Production defects

Production defects that exceed established process control/ action limits are expected to be investigated within Supplier's CAPA system. Production defects are expected to be recorded and analyzed for trend s in order to identify need for further CAPA.

9.5.2 Escapes

Suppliers are expected to take containment action to prevent Nonconforming Product from being integrated with conforming Product. In the event these systems fail, Suppliers are expected to immediately notify MiniMed if Nonconforming Product was shipped to MiniMed or a MiniMed authorized third party, to allow MiniMed to investigate and take containment action.
Suppliers are expected to fully cooperate in any investigation of containment action.

9.5.3 Disposition of nonconforming product

Suppliers are expected to have procedures covering disposition of Nonconforming Product, including review and documentation of disposition decisions. Procedures for rework, retest and re-evaluation of Nonconforming Product are expected to be agreed with MiniMed.

Suppliers are expected to document rework activities in the Device History Record (DHR) or equivalent and submit rework report to MiniMed, upon request.

9.6 Corrective and reventive action (CAPA) system

Suppliers are expected to establish and maintain a CAPA system. The CAPA system is expected to include, at a minimum, the following requirements:

- Analysis of sources of quality data (e.g., Manufacturing process yields, out of control process conditions, production defects, Product disposition records, quality audit records and reports, Complaints, Escapes, Reportable Events, environmental monitoring, Supplier Corrective Action Preventive Action (SCAPA), returned Product or similar Product) using statistical methods and trending where applicable to identify existing and potential causes of Nonconforming Product or other quality problems.
- Investigations to identify the root causes of nonconformances.
- Identification of the actions needed to correct nonconformances and to prevent their recurrence.
- Verification or validation of corrective and preventive actions to assure their effectiveness and to confirm that Product is not adversely affected by the action(s) taken.
- Dissemination of information concerning quality problems or Nonconforming Product to personnel responsible for assuring Product quality.
- Management review of identified quality problems and associated CAPA activities.
- Documentation of CAPA activities and results.

Note: Acceptance of a MiniMed Purchase Order (PO) constitutes acknowledgement that the Supplier has read and understands the expectations of this Playbook

Appendix A: Acronyms

AB	Approved Body
AEO	Authorized Economic Operator
CAPA	Corrective and Preventive Action
CFR	Code of Federal Regulations
COPQ	Cost of Poor Quality
DHF	Design History File
DHR	Device History Record
DRM	Design for Reliability and Manufacturability
ECN	Export Control Number
EU	European Union
FDA	Food and Drug Administration
FMEA	Failure Mode and Effect Analysis (dFMEA & pFMEA)
IPPC	International Plant Protection Convention
ISO	International Standard Organization
MDR	Medical Device(s) Regulation
MSA	Measurement System Analysis
NB	Notified Body
OEM	Original Equipment Manufacturer
PHO	Product Hold Order
PO	Purchase Order
QMS	Quality Management System
SCAPA	Supplier Corrective and Preventive Action
SPC	Statistical Process Control
SOQ	Supplier Owned Quality
UAA	Unannounced Audit
UK	United Kingdom
WCO	World Customs Organization

Appendix B: Terms and definitions

Approved Body: An organization that has been designated by the UK Competent Authority, Medicines and Healthcare products Regulatory Agency (MHRA) to assess whether manufacturers and their medical devices meet the requirements for a Product to be placed on the market in the UK.

Business Continuity Management: A holistic management process that identifies potential impacts that threaten an organization and provides a framework for building resilience with the capability for an effective response that safeguards the interests of its key stakeholders, reputation, brand and value creating activities

Certificate of Conformance (COC): A document attesting that a particular Product is manufactured or serviced in accordance with applicable Quality Management System requirements, Specifications or the Quality Agreement. This may also be referred to as a Certification of Compliance.

Commercial Invoices: The document prepared by the seller which contains the description, value and country of origin of the merchandise being imported into the U.S. It also contains the terms of sale (FOB, CIF, C & F and CFR), the Harmonized Tariff Schedule (HTS) Code and the FDA Product code if applicable.

Component: Any raw material, substance, piece, part, software, firmware, labeling or assembly which is intended to be included as part of the finished, packaged, and labeled device.

Conflict minerals: Minerals mined in conditions of armed conflict and human rights abuses, and which are sold or traded by armed groups.

Contract Manufacturer: A company that manufactures a Finished Medical Device, finished drug, biologic or combination product according to MiniMed Specifications. MiniMed owns the design, maintains control/approval of the Specifications and from a regulatory perspective MiniMed is considered the legal Manufacturer.

Control Plan: A document that identifies key Manufacturing process steps, critical inputs to and critical variables of such steps, and that defines process monitoring control strategies and tools.

Corrective and Preventive Action (CAPA): Describes a process that includes actions needed to correct (correction), avoid recurrence (corrective action), and eliminate the cause of potential Nonconforming Product and other quality problems (preventive action).

Country of Origin (COO): The country in which a Product is wholly grown, produced or manufactured exclusively in that country (this is often referred to as "wholly obtained"). Where a Product consists in whole or in part of materials from another country, the Country of Origin is the last country in which the Product has been substantially transformed into a new and different article of commerce with a name, character and use distinct from that of the article or articles from which it was so transformed. Country of origin for Customs purposes is not always the same as the manufacturing site for regulatory purposes.

C_p: A capability index for a stable process that compares the process capability to the maximum allowable variation as indicated by the tolerance.

C_{pk}: A capability index for a stable process that takes process location as well as capability into account.

Critical Component: A component of a finished device, which if fails could result in a hazard to a patient and/or user and/or is identified in the Product development process as being part of a critical feature or function of the device.

Critical Feature: The process specified by MiniMed for identifying features requiring control.

Customer: MiniMed or the customers of MiniMed.

C-TPAT: The U.S. Customs-Trade Partnership Against Terrorism (C- TPAT) seeks to safeguard the world's vibrant trade industry from terrorists, maintaining the economic health of the U.S. and its neighbors. The partnership develops and adopts measures that add security but do not have a chilling effect on trade.

Design and Development: Activities conducted pursuant to applicable Quality Management System requirements, including FDA's Quality System Requirements, ISO 13485, or both, to design and develop the Product for manufacture.

Design History File (DHF): A compilation of records which describes the design history of a finished device.

Design Input: The physical and performance requirements of a device that are used as a basis for device design.

Design Output: The results of a design effort at each design phase and at the end of the total design effort. The finished design output is the basis for the Device Master Record (DMR). The total finished Design Output consists of the device, its packaging and labeling, and the DMR.

Design Review: A documented, comprehensive, systematic examination of a design to evaluate the adequacy of the design requirements, to evaluate the capability of the design to meet these requirements, and to identify problems.

Design Validation: Establishing by objective evidence that the device specifications conform with user needs and intended use(s).
Design Verification: Confirmation by examination and provision of objective evidence that specified design requirements have been fulfilled.
Device History Record (DHR): A compilation of records containing the production history of a finished device.

Device Master Record (DMR): A compilation of records containing the procedures and specifications for a finished device.

Disaster Recovery Plan: A documented process or set of procedures to protect and recover a business in the event of a disaster.

Export Control Number (ECN): Specifically identifies items that are subject to export control regulations.

Export Control Classification Number (ECCN): ECCNs are five- character alpha-numeric designations used on the U.S. Export Administration Regulation's Commerce Control List (CCL) to identify items for export control purposes. An ECCN categorizes items based on the nature of the product, i.e. type of commodity, software, or technology and its respective technical parameters. Items not listed on the CCL or designated under another government export list are designated EAR99.

Field Corrective Action: Any recall, market withdrawal, stock recovery, safety alert, correction, removal, or field action.

Finished Medical Device: Any device or accessory to any device that is suitable for use or capable of functioning, whether or not it is packaged, labeled, or sterilized.

Gage Repeatability and Reproducibility (GR&R or GRR): Statistical measure to analyze how much variation exists in a gauge, measurement or test equipment.

Lot or Batch: One or more Components or Products that consist of a single type, model, class, size, composition, or software version that are manufactured under essentially the same conditions and that are intended to have uniform characteristics and quality within specified limits.

Playbook: This quality excellence playbook and its appendices.

Manufacturing Material: Any material or substance used in or used to facilitate the manufacturing process, a concomitant constituent, or a by-product constituent produced during the manufacturing process, which is present in or on the finished device as a residue or impurity not by design or intent of the manufacturer.

MiniMed Contract/Agreement: MiniMed documents including purchase orders, purchasing terms and conditions, engineering drawings, Specification requirements, and contracts (quality, supply, development, etc.).

Nonconforming Product: Any Product that does not meet specified requirements, such as:
- Built to an incorrect configuration
- Built with non-validated process parameters or material processes outside of approved parameters
- Built with unapproved Components, counterfeit Components, or Components not meeting Specification

Notified Body (NB): A public or private organization accredited in a member state of the European Union to carry out conformity assessment to determine if a Product to be placed on the market meets certain preordained standards.
OEM: An external legal manufacturer of a Finished Medical Device, drug, biologic or combination product which owns the design, manufacture, and regulatory responsibility.

P_p: A performance index that compares the process performance to the maximum allowable variation as indicated by the tolerance.

P_{pk}: A performance index that takes process location as well as the performance into account.

Product: Components, manufacturing materials, in- process devices, returned devices and Finished Medical Device, drug, biologic and combination product.

Product Hold Order (PHO): The activity that prevents known and potential Nonconforming Product within direct and/or indirect MiniMed control from forward movement.

Qualification: Activity and analysis performed to demonstrate adherence to predetermined criteria. Qualification for a Product means testing and/or inspection conducted according to an approved and controlled protocol to ensure the Product meets Specifications.

Quality System or Quality Management System: The regulatory requirements for the methods used in, and the facilities and controls used for, the design, manufacture, packing, labeling, storage, installation, and servicing.

Records: Written or electronic accounts, notes, data, record of, and information and results obtained from performance of Services.

Restricted Parties: (a) Any entity or individual listed on (i) any of the restricted party lists maintained by the U.S. Government, including the Specially Designated Nationals List and Foreign Sanctions Evaders List administered by the U.S. Department of Treasury's Office of Foreign Assets Controls ("OFAC"), the Denied Parties List, Unverified List or Entity List maintained by the U.S. Department of Commerce Bureau of Industry and Security, and the List of Statutorily Debarred Parties maintained by the U.S. State Department's Directorate of Defense Trade Controls, (ii) the consolidated list of asset freeze targets designated by the United Nations, European Union, and United Kingdom, and any other applicable jurisdictions, or (iii) any other restricted party lists maintained by any governmental or non-governmental entity or agency; or (b) any entity fifty percent (50%) or more owned (either individually or in the aggregate, directly or indirectly) by any entity or individual described in clause (a).

Specification: Any requirement with which a Product, process, Service, or other activity must conform.

Statistical Process Control (SPC): Application of statistical methods such as control charts to analyze a process and determine appropriate actions to take to achieve and improve statistical capability.

Supplier: A provider of Products or Services to MiniMed.
Supplier Owned Quality: Term used to describe the various levels of maturity of our Suppliers Quality Management system to conduct inspections, monitor and act on performance trends and ensure stable and predictable Product performance.

Validation or "Validate": Confirmation by examination and provision of objective evidence that the applicable requirements can consistently be fulfilled.

Wood Packing Material (WPM): Is defined as wood or wood products (excluding paper products) used in supporting, protecting, or carrying a commodity. WPM includes items such as pallets, crates, boxes, reels, and dunnage.

World Customs Organization (WCO) Authorized Economic Operator (AEO) Programs: Customs-to-business partnerships aimed at securing the supply chain and facilitating legitimate low-risk trade.

Appendix C: Standards

- ☐ Annex II AIMDD 90/385/EEC - Active Implantable Devices
- ☐ Annex II MDD 93/42/EEC - Medical Devices
- ☐ Australia - Therapeutics Goods (Medical Devices) Regulations 2002
- ☐ Brazil RDC665/2022 – GMP Requirements for Medical Devices and IVDs
- ☐ California Proposition 65 -Safe Drinking Water and Toxic Enforcement Act of 1986
- ☐ China RoHS: Decree 591 SJ/T 11364-2014
- ☐ CMDR, SOR/98-282 – Canada Medical Devices Regulations
- ☐ EU Battery Directive 2006/66/EC and amendments
- ☐ EU MDR EU MDR: European Union Medical Device Regulation 2017/745 (Annex 1, Chapter II, §10.4.1)
- ☐ EU Packaging Directive 94/62/EC and amendments
- ☐ EU POPs: EU Persistent Organic Pollutants, EC Regulations No. 850/2004, No. 757/2010 and No. 2019/1021 and related amendments, including restriction of perfluorooctanoic acid (PFOA), its salts and PFOA-related substances to 25 ppb (0.0000025 % by weight)
- ☐ EU REACH: Registration, Evaluation, Authorization, and Restriction of Chemicals EU 1907/2006
- ☐ RoHS 2&3: Restriction of Hazardous Substances Directive 2011/65/EU & Amendment 2015/863
- ☐ EU Waste Framework Directive Amendment on the SCIP database (EU 2018/851)
- ☐ EU WEEE: EU Waste Electrical and Electronic Equipment Directive 2012/19/EU
- ☐ Hydrochlorofluorocarbons FDA 40 CFR 82.100 – 82.124
- ☐ Animal Derived Materials, e.g., ISO 22442, EU 722/2012
- ☐ CA Prop 65: California Office of Environmental Health Hazard Assessment Proposition 65
- ☐ Health Canada: Canada – SOR/2014-254
- ☐ Nanomaterials
- ☐ FDA 21 CFR Part 11 - Electronic Records; Electronic Signatures
- ☐ FDA 21 CFR Part 58 - Good Laboratory Practice for Non-Clinical Laboratory Studies (cGLP)
- ☐ FDA 21 CFR Part 210 - Current Good Manufacturing Practice in Manufacturing, Processing, Packaging, or Holding of Drugs; General
- ☐ FDA 21 CFR Part 211 - Current Good Manufacturing Practice for Finished Pharmaceuticals
- ☐ FDA 21 CFR Part 312 - Investigational New Drug Application
- ☐ FDA 21 CFR 801.437 - Natural Rubber Latex
- ☐ FDA 21 CFR Part 803 - Medical Device Reporting
- ☐ FDA 21 CFR Part 807 - Establishment Registration and Device Listing for Manufacturers and Initial Importers of Devices
- ☐ FDA 21 CFR Part 820 - Quality Management System Regulation
- ☐ Food and Drug Regulations, C.R.C., c. 870, Part C, Division 2, Good Manufacturing Practices (GMPs)
- ☐ ISO 13485 / EN ISO 13485 – Medical Devices – Quality management systems – Requirements for regulatory purposes
- ☐ ISO 14001 Environmental Management Systems
- ☐ ISO14971 / EN ISO14971 – Medical devices –
- ☐ Application of risk management to medical devices
- ☐ IVDD 98/79/EC
- ☐ Korea Medical Device Act
- ☐ Mexico, Ley General de Salud
- ☐ MHLW GMP Ordinance #169 – Japan Quality Management System Compliance
- ☐ Natural Rubber Latex FDA 21 CFR 801.437
- ☐ SMDO – Switzerland Medical Devices Ordnance – Switzerland (812.213)
- ☐ The Safety of Human Cells, Tissues and Organs for Transplantation (CTO) Regulations, SOR/2007-118
- ☐ UK Medical Devices Regulation – UK MDR 2002 (SI 618) as amended by the EU exit regulations 2019 (SI 791) and 2020 (SI 1478)

1800 Devonshire Street
Northridge, CA 91325
Tel: 1-800-646-4633

Toll-free: 1-800-646-4633
(24-hour technical support for
physicians and medical professionals)

MiniMed.com