1. **Purpose**

To describe the requirements for compliance with the Medical Device Directive 93/42/EEC for the manufacture, distribution and related activities for our medical devices intended for sale in the European Union.

1. **Scope**

This procedure pertains to all medical device related products and their accessories which are intended for distribution in the European Union.

1. **General**
   1. **Definitions**
   * **Authorized Representative (AR):** The person or organization in the European Community appointed by the company to act on its behalf in carrying out certain tasks required by the Medical Device Directive.
   * **Competent Authority (CA):** A government or regulatory authority of a given member state for a given Directive. Competent Authorities are responsible for appointing accreditation bodies and for notifying organizations for a specific Directive to the European Commission. The manufacturer is obligated to deal through the Competent Authority in the country of its Notified Body.
   * **Essential Requirements (ER)**: Annex 1 of MDD93/42/EEC listing detailing essential principals of safety that a device must meet in order for it to be placed into the EU.
   * **EU**: European Union
   * **Management Representative:** An individual with the authority and responsibility to ensure that a Quality System is established and maintained in accordance with the requirements of the Quality Manual and applicable regulations and standards.
   * **MDD**: Medical Device Directive
   * **Notified Body:** An organization that has been designated by European authorities to carry out conformity assessments under the Medical Device Directive, and selected as part of its certification to the Medical Device Directive.
   * **QMS:** Quality Management System
   1. **Responsibilities**
   * **The Quality and Regulatory Affairs** are responsible for adherence to the Medical Device Directive (MDD 93/42/EEC) and associated directives and international standards pertaining to medical device distribution in the European Union.
   1. **Equipment and Materials –** N/A
   2. **Safety Precautions –** N/A
   3. **Training Requirements –** Quality and Regulatory Affairs are required to be trained to this procedure and the training documented.
   4. **References**
   * **MDD 93/42/EEC** – Medical Device Directive
2. **Procedure**
   1. The company designs, develops, manufactures and services products that are intended to be distributed globally. The products that are intended to be distributed to the EU will be authorized to bear the CE mark granted by our Notified Body.
   2. The company maintains a Quality Management System compliant with ISO 13485, the Medical Device Directive, and other relevant standards and directives that support product creation and distribution. The QMS is periodically audited by an authorized notified body to ensure compliance and relevancy.
      1. The authorized notified body will be notified of any plans for substantial changes to the QMS or where the product range covered by the scope of registration will be expanded.
   3. The company has selected an Authority European Representative to represent our company in the European Union.
      1. The company will label medical devices placed on the market with the appropriate Notified Body CE marking and the name and relevant contact information of the Authorized Representative.
      2. Authorized Rep Contact Information is maintained by the regulatory department.
      3. The company will prepare appropriate technical documentation to support product distribution in the EU. The technical file will be made available to a Competent Authority for a minimum of 5 years after the last date of manufacture for a product.
      4. In combination, the company and the Authorized Representative will provide for product vigilance within the EU. The AR will receive copies of all notifications sent to Competent Authorities. Conversely, the AR will notify the company of any complaint or correspondence received.
      5. Additionally, the AR is obligated to inform the company of any new or amended regulations for any EU member nation.
   4. Product certification is documented on a Declaration of Conformity (DoC) in compliance with the requirements of the Medical Device Directive. The DoC identifies:
      * Manufacturer name and address,
      * Authorized (EU) Representative,
      * Product Name(s) and Model reference number(s),
      * Product classification according to Annex IX of the MDD,
      * GMDN Codes,
      * QMS certification information, and
      * Notified Body name and address
      1. A technical file will be created and maintained for product for sale and distribution in the EU. Amongst other things, the technical file will contain:
      * Description about the device(s)
      * Reference to the ER Checklist
      * References to Risk Assessment(s) performed
      * References to Clinical Evaluation(s)/Literature Study(ies)
      * References to Verification & Validation performed
      * Reference to Manufacturing Plan & Validation
      * References to Product Labeling
      * Reference to the Declaration of Conformity
   5. The company has included the required details for compliance to the Medical Device Directive by documented reference to the elements of Medical Device Reporting, Vigilance (Product Recall), Post Market Surveillance and other pertinent procedures.
   6. The Authorized Representative will be informed of any plans to conduct Clinical Investigations within the EU. In turn, the AR will ensure that the Competent Authority(ies) are properly notified and will maintain the appropriate vigilance and records throughout the investigation.
3. **Revision History**

| **Rev #** | **Doc #** | **Effective Date** | **CHO** | **Description of Change** |
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| 01 | QP-0028 |  |  | Initial release of the EU MDD Procedure |