TERUMO CARDIOVASCULAR

TITLE: Supplier Questionnaire Request

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| **Company Name** | **Supplier Contact:** | | **Name** | | | | | | **Title** |
| **Company Website** | **Email** | | | | | | **Phone** |
| **Manufacturing/ Service Location** | | **Other facilities used by Terumo CV? (e.g. shipping)** | | | | | | | **Remit  N/A** |
| **Street Address**    **City, State**    **Postal Code, Country**    **Phone** | | Yes  No  If yes, please explain: | | | | | | | **Street Address**    **City, State**    **Postal Code, Country**    **Phone** |
| How long in operation? | | | | | Total number of employees at this site? | | | | |
| Number in Quality:       Manufacturing:       Engineering:       Temporary: | | | | | | | | | |
| Is your company registered with the FDA? | | | | | | | FDA registration number, if applicable | | |
| Percentage of customers in medical device industry? | | | | | | | | Size of Facility in square feet: | |
| Scope and overall summary of primary products / services provided at this facility: | | | | | | Does your company have a quality policy?  Yes  No  If yes, please state or attach policy | | | |
| Does your company rely on third party contract manufacturers? | | | | Yes  No  N/A  If yes, please explain: | | | | | |
| Does your company provide sterilization services or contract a 3rd party sterilization service provider? | | | | Yes  No  N/A  If yes, please explain: | | | | | |
| Does your company rely on third party design/engineering providers? | | | | Yes  No  N/A  If yes, please explain: | | | | | |
| Does your facility have a clean room with established environmental controls? | | | | Yes  No  N/A  If yes, please explain: | | | | | |

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| **#** | **Question** | **Scale Rating** | | |
| **Established:**  Defined, documented (in writing or electronically), and implemented | **Informal System:**  May have procedure but not documented or may be documented but no formal procedure exists | **Not Established:**  Process is not defined, documented (in writing or electronically), and implemented |
| **1** | Does your company’s Quality Management System (QMS) currently meet national or international standards (i.e. ISO 9001)? | 5: QMS is certified to ISO standard | 3: QMS exist but not certified to ISO standard | 1: No documented QMS |
| **2** | Does your company have a Quality Manual that describes the systems and controls to assure the quality of its products and/or services? | 5: Quality Manual established | 3: Quality Manual documented but not rev controlled | 1: No Quality Manual established |
| **3** | Does your company have a Contract Review Policy/Procedure? | 5: Policy/ Procedure established | 3: Informal system exists | 1: No Policy/ Procedure established |
| **4** | Does your company utilize a documented engineering change control system (EC/ECO) Policy/Procedure? | 5: Policy/ Procedure established | 3: Informal system exists | 1: No Policy/ Procedure established |
| **5** | Does your company have a Document and Quality Records Control and Retention Policy/Procedure? | 5: Policy/ Procedure established | 3: Informal system exists | 1: No Policy/ Procedure established |
| **6** | Does your company have a Purchasing Policy/Procedure that includes requirements for maintaining an Approved Supplier List (ASL) for product and service providers with product and/or quality system impact? | 5: Policy/ Procedure established | 3: Informal system exists | 1: No Policy/ Procedure established |
| **7** | Does your company use Good Documentation Practices (GDP’s)? | 5: Policy/ Procedure established | 3: Informal system exists | 1: No Policy/ Procedure established |
| **8** | Does your company utilize controlled travelers, work orders, bill of materials, or job routers? | 5: Documentation established | 3: Informal system exists | 1: No documentation established |
| **9** | Does your company have an Identification and Traceability Policy/Procedure that can be utilized to determine date of manufacture/service and product/equipment status? | 5: Policy/ Procedure established | 3: Informal system exists | 1: No Policy/ Procedure established |
| **10** | Does your company have work instructions that are used to control manufacturing (or service) processes, inspection operations and product/equipment release testing? | 5: Work Instructions established | 3: Informal process exists | 1: No Work Instructions established |
| **11** | Does your company have an Inspection and Testing Policy/Procedure? | 5: Policy/ Procedure established | 3: Informal system exists | 1: No Policy/ Procedure established |
| **12** | Does your company have a Training Policy/ Procedure? | 5: Policy/ Procedure established | 3: Informal system exists | 1: No Policy/ Procedure established |
| **13** | Does your company have Calibration Policy/Procedure?  N/A | 5: Policy/ Procedure established | 3: Informal system exists | 1: No Policy/ Procedure established |
| **14** | Does your company have a Control of Nonconforming Material/Product/Service (NCR) Policy/Procedure? | 5: Policy/ Procedure established | 3: Informal system exists | 1: No Policy/ Procedure established |
| **15** | Does your company have a Corrective and Preventive Action (CAPA) and Complaint Handling Policy/Procedure? | 5: Policy/ Procedure established | 3: Informal system exists | 1: No Policy/ Procedure established |
| **16** | Does your company have a Handling, Storage, Packaging, and Delivery Policy/Procedure?  N/A | 5: Policy/ Procedure established | 3: Informal system exists | 1: No Policy/ Procedure established |
| **17** | Does your company have a Statistical Techniques and Sampling Plan Policy/Procedure? N/A | 5: Policy/ Procedure established | 3: Informal system exists | 1: No Policy/ Procedure established |
| **18** | Does your company have a Process Validation Policy/Procedure? N/A | 5: Policy/ Procedure established | 3: Informal system exists | 1: No Policy/ Procedure established |
| **19** | Does your company have a Risk Management Policy/Procedure? | 5: Policy/ Procedure established | 3: Informal system exists | 1: No Policy/ Procedure established |
| **20** | Does your company have an independent quality organization/department? | 5: Independent Quality Department | 3: Quality Department is not independent | 1: No Quality Department |

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| **Supplier Questionnaire Completion** *(To be completed by Supplier)* | | |
| **Supplier’s Representative** | Sign: | Print: |
| Date: | Title: |
| **Questionnaire Return Instructions**  *Please return completed Supplier Questionnaire Request via e-mail*  **E-mail:**  Attn: Supplier Quality Engineering [TCVSELW.SQE@terumomedical.com](mailto:TCVSELW.SQE@terumomedical.com) | | |

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| **Questionnaire Evaluation** *(To be Completed by TCV)* |
| Supplier Total Scale Rating (Total Points Questions 1 – 20): |
| This Supplier Questionnaire was reviewed, and responses are: (check one)  Acceptable  Not Acceptable  **Comments:** |

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| **Approvals** | | | | |
| **Supplier Quality Engineer (or Designate)** | **Print** | **Title** | **Signature** | **Date** |
| **Supplier Quality Engineering Management** | **Print** | **Title** | **Signature** | **Date** |