Reference WI – Supplier Proposal for Change – Ann Arbor, 852642, for instructions.

# Supplier Change Proposal

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| **Supplier Proposal for Change (SPC)** |
| Supplier Name:      Supplier Contact Name:      Supplier Email:       | Terumo Part Numbers - Revisions affected:      | Proposed Implementation Date:       |
| Brief Description of **What** is Changing: | Brief Description of **Why** the change is needed: |
| *(Describe in detail WHAT is changing. Provide an outline of the current state and the future state including what documentation would change such as Control Plans, Work Instructions, pFMEA, etc.)* | *(Describe in detail WHY the change is needed (e.g., Increased Capacity, Material Availability, Quality Improvement, Cost Savings, CAPA, Audit Findings, New Processes, New Equipment, etc.)* |
|       |       |
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| --- | --- |
| Area of Change | Changing |
| Yes | No |
| Process Change*(****Changes related to:*** *Control Plans, Work Instructions, pFMEAs, Sampling Plans, Equipment Add/Remove/Changes, Facility Moves, Validation Changes, Test Method Changes, Tooling Changes, Raw Material)* | [ ]  | [ ]  |
| Sub Tier Supplier Change*(****Changes related to:*** *New or Alternate Sub-Tier Suppliers)* | [ ]  | [ ]  |
| Design Change*(****Changes related to:*** *Terumo Prints, Terumo Design Specifications or Other Terumo Related Documents)* | [ ]  | [ ]  |
| [ ]  N/A Other:       |

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| Supplier’s Approval***NOTE: The proposed change cannot be implemented until it has been reviewed and properly dispositioned by Terumo.*** |
| Print Name:       | Title:       | Date:       |
| Comments:       |
|  | **Supplier Completion Stops Here** |  |

# SPC Number:

|  |  |  |
| --- | --- | --- |
| SPC number:       | Business Unit: [ ]  CDI [ ]  EM [ ]  Other:       | Date:       |

# Impacted Items:

| Item №: | Describe the process(es) that are changing: |
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|       |       |

# Process Changes: [ ]  N/A Change does not affect Process Change

## Manufacturing Process [ ]  N/A Change does not affect the Manufacturing Process

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|  Is this for new Process / Equipment / Tooling? [ ]  **Yes** [ ]  **No**[ ]  **Process** [ ]  **Equipment** [ ]  **Tooling** [ ]  **Method of Testing** |
| Should the new process/change be validated? [ ]  **Yes** [ ]  **No****If no,** [ ]  reviewed process validation criteria per WI – Process Validation, 812426Provide rationale:       |
| Should the control documentation be updated (Process Flow, PFMEA, Control Plan, WI)? [ ]  **Yes** [ ]  **No** [ ]  **N/A**If no or N/A, provide rationale:       |
| If there is an existing test at Terumo CVS Incoming Quality, will it be impacted by the change?[ ]  **Yes** [ ]  **No**If no, provide rationale:       |

## Site of Manufacture [ ]  N/A Change does not affect Site of Manufacture

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| Is a transfer plan required? [ ]  **Yes** [ ]  **No**If no, provide rationale:      [ ]  Reviewed transfer plan from the supplierDoes the transfer plan require the processes to be re-validated? [ ]  **Yes** [ ]  **No**Verification method:      **If no,** [ ] reviewed process revalidation criteria per WI – Process Validation, 812426Provide rationale:       |

## Raw Material [ ]  N/A Change does not affect Raw Material

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| Is the material equivalent? [ ]  **Yes** [ ]  **No**Verification method:       |
| Should the material change be validated? [ ]   **Yes** [ ]  **No**Verification method:      **If no,** [ ]  reviewed process validation criteria per WI – Process Validation, 812426Provide rationale:       |

# Sub Tier Supplier Change [ ]  N/A Change does not affect Sub Tier Supplier Change

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| Should the change be validated? [ ]  **Yes** [ ]  **No**Verification method:      **If no,** [ ] reviewed process validation criteria per WI – Process Validation, 812426Provide rationale:       |

# Design Change [ ]  N/A Change does not affect Design

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| Is a revision level change required to the top level object in Matrix? [ ]  **Yes** [ ]  **No**Verification method:      If no, provide rationale:       |
| Does the change impact any Terumo CVS documents? [ ]  **Yes** [ ]  **No**Verification method:      If no, include rationale:       |

# Other [ ]  N/A

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| Should the change be validated? [ ]  **Yes** [ ]  **No** [ ]  **N/A**Verification method:      **If no,** [ ]  reviewed process validation criteria per WI – Process Validation, 812426Provide rationale:       |
| Other:       [ ]  **N/A** |

# Review, Approvals, Effectivity and Outcome:

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| --- |
| **Completed By:** |
|  |
| Signature Print Name DateAddition Information/Comments (if applicable):       |
| **SPC Board Review** |
| SPC Board Review Date(s):      Disposition: [ ]  Approve with ECR [ ]  Approve without ECR [ ]  Reject ECR # (if applicable):       |
| [ ] N/A Notes:       |
| **Proposed Effectivity** |
| [ ]  **Lot Number:**      | [ ]  **Date:**      | [ ]  **Purchase Order:**      | [ ]  **Other – Provide Details:**       |
| Is a Primary Location Change Needed? [ ]  Yes [ ]  No |
| Is a Site Evaluation Needed? [ ]  Yes [ ]  No |
| **SPC Board Approvals:** |
| **Quorum Member** | **Printed Name** | **Signature** | **Date** |
| Product Development Management: |  |  |  |
| Materials Management Representative: |  |  |  |
| DQA Representative: |  |  |  |
| SQE Management Representative: |  |  |  |
| **SPC Outcome:** |
| [ ] Approved without ECR:  | [ ] You can begin immediate implementation of the proposed change(s) no additional documentation from your organization is needed at this time.[ ]  You **may not implement** the proposed change(s) until the following information is updated to support the change: [ ] Control Plan [ ] Work Instructions [ ] pFMEA[ ] Other:      The Terumo Change Review Number is:       |
| [ ] Approved with ECR:  | [ ] Terumo needs to make internal changes and you cannot implement the proposed change(s) until the internal changes are completed. You will be contacted when the internal changes are ready to be implemented.[ ]  Terumo needs to make internal changes however the proposed change(s) may be implemented prior to completion of the internal changes. |
| [ ] Rejected | The proposed change was rejected and cannot be implemented.Reason for Rejection:       |
| **Supplier Acknowledgement:** By signing below you attest that you understand and will follow the SPC Board’s decision. |
|  |  |  |
| Printed Name / Title | Signature | Date |

# Effectivity Notes, SPC Closure

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| **Effectivity Notes:** |
|       |
| **Closure Information** |
| **Action** | **Date** | **Date** | **Days** |
| Time to Review |       |       |       |
| Time to Disposition |       |       |       |
| Time to Implement |       |       |       |
| **Supplier Quality Representative Review and Approval** |
|  |  |  |
| Printed Name / Title | Signature | Date |
| **SQE Management Review and Approval** |
|  |
| Printed Name / Title | Signature | Date |
|  |  |  |
| [ ] N/A **Attachments:** |
|       |