TERUMO CARDIOVASCULAR

TITLE: Supplier Proposal for Change

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**To be completed by Supplier: Sections 1-5**

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| **Section 1: Supplier Information**  |
| Supplier Name:  |       | Date:        |
| Supplier Contact:  |       | Telephone: |       |
| Supplier Signature:       | Email:       |
| **Section 2: Category of the Proposed Change (check all that apply)** |
| **[ ]** Source of Material | **[ ]** Method of Testing |
| **[ ]** Site of Manufacture | **[ ]** Contractor for Manufacturing Process |
| **[ ]** Composition of any Raw Material | **[ ]** Contractor for Testing  |
| **[ ]** Manufacturing Process | **[ ]** Supplier ResponsibleDesign  |
| **[ ]** Instructions for Use | **[ ]** Label/Packaging |
| [ ]  Terumo CV Design, Specification, Drawing, or Part | [ ]  Other (provide detail):       |
| **Section 3: Detail of the Proposed Change (provide red-lined print if applicable)** |
| Affected Terumo CV Part Number(s) and Part Description(s):       |
| Description of Proposed Change:       |
| Reason for Requesting the Proposed Change:       |
| List Affected Document(s):        |
| **Ship to Location(s):** | **[ ]** Elkton, MD | **[ ]** Ashland, MA |
| **Section 4: Proposed Effectivity / Implementation of Change** |
| **[ ]  Lot Number:** | **[ ]  Date:** | **[ ]**  **Purchase Order:** | **[ ]**  **Other (provide detail):**  |
| Additional Detail:       |
| **Section 5: Validation** |
| **[ ]  Protocol and / or results attached (list attachments):**  |
| **[ ]  None completed (provide rationale):**  |

Return completed form to: Terumo CV Elkton Supplier Quality (TCVSELW.SQE@terumomedical.com) or a Terumo CV Materials Management Representative.

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| **Terumo CV Approval Section (Terumo CV ONLY)** |
| **[ ]  Terumo CV Approves the Proposed Change** **Outcome of the change proposal assessment to Terumo CV:****[ ]  Change required. Provide Change Control Number :****[ ]  No change required. Provide Rationale :** |
| **[ ]  Terumo CV Does Not Approve the Proposed Change** **Provide Rationale :** |
| **Terumo CV Elkton Pre-Approval** |
| **[ ]  N/A**  |
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| Name  |  | Signature  |  | Date  |
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| Terumo CV Engineering /Technical Manager |  |  |  |  |
| Name  |  | Signature  |  | Date  |
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| Terumo CV Supplier Quality Engineering Manager |  |  |  |  |

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| **Terumo CV Elkton Final Approval** |
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| Name  |  | Signature  |  | Date  |
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| Terumo CV Business Unit Manager |  |  |  |  |
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| Name  |  | Signature |  | Date  |
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  Terumo CV Supplier Quality Engineering Manager |
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| The following signatures are only required if a change order was not used to approve this change.[ ]  N/A CO (attach workflow) |
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| Name  |  | Signature  |  | Date  |
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| Terumo CV Engineering /Technical Manager |  |  |  |  |
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| Name  |  | Signature  |  | Date  |
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| Terumo CV Regulatory Affairs Representative |  |  |  |  |
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