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