

Supplier Waiver Request Form

SECTION I: To be completed by Supplier

BACKGROUND

| | | | |
|-------------------------|-------------------------------|------------------------|--|
| Supplier Name | | | |
| Supplier Address | | | |
| Supplier Contact Name | | Supplier Contact Title | |
| Supplier Contact e-mail | | Supplier Phone Number | |
| Submission Date | Click or tap to enter a date. | | |

AFFECTED TMC PART NUMBER(S)

| | | | |
|----------------------------|--|-----------------------------------|--|
| TMC Part Number & Revision | | Part Description | |
| Supplier Lot Number(s) | | PO Number(s) | |
| Quantity | | Comments / Additional Information | |

REQUEST FOR WAIVER

| | |
|--|--|
| Purpose of Waiver | <input type="checkbox"/> Deviation (prior to production or service) <input type="checkbox"/> Authorization to send product or service not meeting requirements to TMC (post-production or service) <input type="checkbox"/> Rework of product at Supplier that is not meeting requirements. <input type="checkbox"/> Other (add Comments below) Comment: |
| Duration of Waiver | <input type="checkbox"/> One-Time Use <input type="checkbox"/> Recurring through date: Click or tap to enter a date. <input type="checkbox"/> Recurring for the following lots/batches: Comment: |
| Specification / Requirement Not Being Met | |
| Description of Waiver Request <i>Include summary of any testing or evaluation performed and root cause summary, if known.</i> | |

CORRECTIVE ACTION AND VERIFICATION OF EFFECTIVENESS (VOE) PLAN

Describe plan to return to original state and prevent recurrence

| | | | |
|------------------------|--|----------|-------------------------------|
| Corrective Action Plan | | Due Date | Click or tap to enter a date. |
| VOE Plan | | | |

Send completed document in Microsoft Word format along with any supporting data, evaluation, or images to: TMCsupplierChangeNotification@terumomedical.com. Copy TMC Supplier Quality representative, if known.

SUPPLIER SHALL NOT SHIP PRODUCT LISTED IN THIS WAIVER WITHOUT PRIOR WRITTEN APPROVAL BY TMC THROUGH SECTION II OF THIS FORM.

If approved by TMC, a copy of Waiver (completed through Section II) must accompany shipment of product.

SECTION II: To be completed by TMC

WAIVER REVIEW

| | |
|---|--|
| Comments <i>Include any additional evaluation performed by TMC, if applicable.</i> | |
| Determination | <input type="checkbox"/> Approved <input type="checkbox"/> Denied |

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| NC # <i>Required only when affected product will be sorted/reworked at TMC</i> | | |
|---|------|----------------|
| APPROVALS <i>(Add rows as needed)</i> | | |
| Functional Area | Name | Signature/Date |
| Supplier Quality Engineering | | See eDMS |
| Director, Supplier Quality Engineering | | |
| Engineering Manager | | |

| SECTION III: To be completed by TMC | | | |
|--|------|----------------|-------------------------------|
| WAIVER CLOSURE | | | |
| Evidence of Corrective Action Implementation | | Date Complete | Click or tap to enter a date. |
| VOE Results | | Date Complete | Click or tap to enter a date. |
| CLOSURE <i>(Add rows as needed)</i> | | | |
| Functional Area | Name | Signature/Date | |
| Supplier Quality Engineering | | See eDMS | |
| Director, Supplier Quality Engineering | | | |
| Supplier Quality Engineering Analyst | | | |