

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			