

Section I – Supplier Change Information (To be completed by supplier)

Supplier Name:	Click or tap here to enter text.		
Supplier Address:	Click or tap here to enter text.		
Supplier Representative Name:	Click or tap here to enter text.	Supplier Representative e-mail:	Click or tap here to enter text.
TMC Part Number	Document Number(s) and Revision	MSS/Drawing Number(s) and Revision	
Click or tap here to enter text.	Click or tap here to enter text.	Click or tap here to enter text.	
<i>Add rows as needed for Part/MSS/Drawing Numbers.</i>			
Proposed Change (What): <i>Describe the current state and the proposed change in detail</i>	Current State: Proposed Change:		
Reason for Change (Why): <i>Explain why the proposed change is needed and/or recommended</i>	Click or tap here to enter text.		
Supplier Reference Document #: <i>(i.e., Change Order, CAPA, NC, SCR, Quality Plan, Quality Agreement)</i>	Click or tap here to enter text.		
Proposed Implementation Date (When): <i>Proposed date of implementation of change</i>	Date: Rationale for Proposed Implementation Date: Last day for TMC to receive material prior to change <i>(if not applicable, explain):</i> Quantity available to purchase prior to change <i>(if not applicable, explain):</i>		
Qualifications / Validations Planned and/or Performed by Supplier:	<input type="checkbox"/> Yes <i>(Provide description of planned/completed activities to qualify this change. Provide objective evidence upon completion of activity to TMC).</i> <input type="checkbox"/> No <i>(Provide a Rationale):</i>		

Please send the completed document as a Microsoft Word file and any relevant documentation to tmcsupplierchangenotification@terumomedical.com.
STOP: The remainder of the form is for TMC use.

Section II – TMC Inventory Impact Assessment – For internal use at TMC only. Complete all fields or record “NA”.

Inventory Impact Assessment (Prior to implementing change) <i>(This Section will be completed by Production Planning/Buyer)</i>			
Current Inventory On-hand:	Click or tap here to enter text.	Current Inventory Run-Out Date: <i>(Inventory on-hand and current open PO's)</i>	Click or tap here to enter text.
Are Open PO's Affected:	<input type="checkbox"/> Yes <input type="checkbox"/> No	Last Time Buy Required: <i>(Consider expiration dating and available storage when submitting last time buy)</i>	<input type="checkbox"/> Yes <input type="checkbox"/> No Inventory Run-Out date:
Impacted TMC Product Family/Families:	Click or tap here to enter text.	Actions/Comments:	
Date Completed:			

Section III – TMC Assessment – Complete all fields

Change Assessment <i>(This section will be completed by Supplier Quality Engineering and Engineering)</i>					
Supplier ID:	Click or tap here to enter text.	Impacted TMC Site(s):	Click or tap here to enter text.	Change Category:	Choose an item.
Responsible	Assessment	Yes	No	Comments (If No, rationale is required)	
Supplier Quality Engineering	Material Qualification	<input type="checkbox"/>	<input type="checkbox"/>		
	Audit/Assessment	<input type="checkbox"/>	<input type="checkbox"/>		
	ASL/SAP update	<input type="checkbox"/>	<input type="checkbox"/>		

	Incoming Inspection/Test Method update	<input type="checkbox"/>	<input type="checkbox"/>	
	Part Inspection/Certification Status update	<input type="checkbox"/>	<input type="checkbox"/>	
	Other	<input type="checkbox"/>	<input type="checkbox"/>	
Engineering	Confirmation build/process validation	<input type="checkbox"/>	<input type="checkbox"/>	
	Product performance testing	<input type="checkbox"/>	<input type="checkbox"/>	
	Packaging or Shipping Assessment	<input type="checkbox"/>	<input type="checkbox"/>	
	Sterilization Assessment	<input type="checkbox"/>	<input type="checkbox"/>	
	Aging	<input type="checkbox"/>	<input type="checkbox"/>	
	Bioburden/LAL Assessment	<input type="checkbox"/>	<input type="checkbox"/>	
	Biocompatibility Assessment	<input type="checkbox"/>	<input type="checkbox"/>	
	MSS/Drawing update or creation	<input type="checkbox"/>	<input type="checkbox"/>	
	Design control documentation update	<input type="checkbox"/>	<input type="checkbox"/>	
	Labeling/Artwork update	<input type="checkbox"/>	<input type="checkbox"/>	
	Manufacturing Procedure(s) update	<input type="checkbox"/>	<input type="checkbox"/>	
	Material Master or BOM update	<input type="checkbox"/>	<input type="checkbox"/>	
Other	<input type="checkbox"/>	<input type="checkbox"/>		

Regulatory Assessment
(This section will be completed by TMC Regulatory Affairs)

US:	<input type="checkbox"/> No prior approval regulatory submission required. <input type="checkbox"/> 30-Day Notice <input type="checkbox"/> Internal Update <input type="checkbox"/> Other:	Canada:	<input type="checkbox"/> No prior approval regulatory submission required. <input type="checkbox"/> License Amendment <input type="checkbox"/> Internal Update <input type="checkbox"/> Other:
EU:	<input type="checkbox"/> No prior approval regulatory submission required. <input type="checkbox"/> Significant Change Notification <input type="checkbox"/> Other:	International Regulatory:	Regulatory Notification/PCN Required: <input type="checkbox"/> No <input type="checkbox"/> Yes Comments:

TMC RA Document Revision Required: <i>(i.e., SSCP, Technical Document)</i>	<input type="checkbox"/> Yes <i>(If Yes list document ID(s)):</i> <input type="checkbox"/> No
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Comments *(Leave blank if not applicable):*

Change Assessment and Regulatory Assessment Conclusion
(This section will be completed by Supplier Quality)

Change Request (CR) and/or DCO Required: <i>(Based on the assessment requirements above, refer to 04-1TSOP-01 to determine if a CR and/or DCO is required.)</i>	<input type="checkbox"/> Yes <input type="checkbox"/> No CR / DCO Owner: CR / DCO#:
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Section IV – TMC Assessment Reviewed

Function	Name Printed	Function	Name Printed
Engineering:		Production Planning/Buyers:	
Supplier Quality:		Supplier Quality Management:	
Regulatory Affairs:		Other (List Function):	

Section V – SCN Closure – This section will be completed by SCN Cross-Functional Team

Action #	Action:	Evidence of Completion <i>(i.e., CO/DCO#, Validation#, SCN Attachment#...):</i>
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<i>Add rows as needed.</i>		
Comments: <i>(As applicable)</i>		
Implementation Information: <i>(Part#, Lot/Work Order#, Date, PO#, or etc.)</i>		
SCN Closure: <input type="checkbox"/> SCN Approved/Completed <input type="checkbox"/> SCN Denied/Canceled for the following reason:		
Function	Name Printed	Signature/Date
Engineering:		See eDMS
Supplier Quality:		
Regulatory Affairs:		
Production Planning/Buyers:		
Other (List Function):		
Supplier Quality Management:		
SQE Analyst:		