Supplier Change Notification

SCN #

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.
Add rows as needed for Part/MSS/Drawing Numbers.		

Proposed Change (What): *Describe the current state and the proposed change in detail*	Current State: Proposed Change:
Reason for Change (Why): *Explain why the proposed change is needed and/or recommended*	Click or tap here to enter text.
Supplier Reference Document #: *(i.e., Change Order, CAPA, NC, SCR, Quality Plan, Quality Agreement)*	Click or tap here to enter text.
Proposed Implementation Date (When): *Proposed date of implementation of change*	Date: Rationale for Proposed Implementation Date: Last day for TMC to receive material prior to change *(if not applicable, explain):* Quantity available to purchase prior to change *(if not applicable, explain)*:
Qualifications / Validations Planned and/or Performed by Supplier:	☐ Yes *(Provide description of planned/completed activities to qualify this change. Provide objective evidence upon completion of activity to TMC).* ☐ No *(Provide a Rationale)*:

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)* *(This Section will be completed by Production Planning/Buyer)*			
Current Inventory On-hand:	Click or tap here to enter text.	**Current Inventory Run-Out Date:** *(Inventory on-hand and current open PO's)*	Click or tap here to enter text.
Are Open PO's Affected:	☐ Yes ☐ No	**Last Time Buy Required:** *(Consider expiration dating and available storage when submitting last time buy)*	☐ Yes ☐ 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 *(This section will be completed by Supplier Quality Engineering and Engineering)*			
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	☐	☐	
	Audit/Assessment	☐	☐	
	ASL/SAP update	☐	☐	

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

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

US:	☐ No prior approval regulatory submission required. ☐ 30-Day Notice ☐ Internal Update ☐ Other:	**Canada:**	☐ No prior approval regulatory submission required. ☐ License Amendment ☐ Internal Update ☐ Other:
EU:	☐ No prior approval regulatory submission required. ☐ Significant Change Notification ☐ Other:	**International Regulatory:**	Regulatory Notification/PCN Required: ☐No ☐Yes Comments:

TMC RA Document Revision Required: *(i.e., SSCP, Technical Document)*	☐ Yes *(If Yes list document ID(s)):* ☐ No
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: *(Based on the assessment requirements above, refer to 04-1TSOP-01 to determine if a CR and/or DCO is required.)*	☐ Yes ☐ No CR / DCO Owner: CR / DCO#:

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.e., CO/DCO#, Validation#, SCN Attachment#...):*

Supplier Change Notification

Add rows as needed.

Comments: *(As applicable)*	
Implementation Information: *(Part#, Lot/Work Order#, Date, PO#, or etc.)*	
SCN Closure:	☐ SCN Approved/Completed ☐ 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:		