

**Section I – Supplier Change Information Section** – Please complete the following section to describe the proposed change request. Contact TMC Supplier Quality representative with any questions. Send the completed document as a Microsoft Word file, as well as any relevant documentation (quotes, process flow, etc.) on the change with this completed section of the form.

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 Title:	Click or tap here to enter text.
Supplier Representative e-mail:	Click or tap here to enter text.	Supplier Representative Phone Number:	Click or tap here to enter text.
Submission Date:	Click or tap to enter a date.		

**Impacted Document / TMC Part Number(s)**  
*(Add additional rows, as necessary, for document/part/drawing numbers)*

Document Number(s) and Revision	Document Title	TMC Part Number	TMC Part Description	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.	Click or tap here to enter text.	Click or tap here to enter text.

<b>Proposed Change (What)</b> <i>Describe the proposed change in detail:</i>	Click or tap here to enter text.
<b>Reason for Change (Why)</b> <i>Explain why the proposed change is needed and/or recommended:</i>	Click or tap here to enter text.
<b>Supplier Change Order #, CAPA #, NC #, SCR #, Quality Plan #, etc.</b> <i>Provide Document Number</i>	Click or tap here to enter text.
<b>Related Supplier Change Notification # (as applicable)</b> <i>Provide Document Number</i>	Click or tap here to enter text.
<b>Category of the Proposed Change</b> <i>Select all applicable check boxes:</i>	<input type="checkbox"/> Composition of Raw Material <input type="checkbox"/> Site of Manufacture <input type="checkbox"/> Source of Material <input type="checkbox"/> Manufacturing Process <input type="checkbox"/> Major change in quality system/status <input type="checkbox"/> Method of Testing <input type="checkbox"/> Significant change in organizational structure that may affect manufacturing and quality of supplier component <input type="checkbox"/> Change within the supply chain or manufacturing process that significantly alter environmental impact <input type="checkbox"/> Terumo Design, Specification, Drawing or Part <input type="checkbox"/> Supplier Design, Specification, Drawing or Part <input type="checkbox"/> Contractor for Manufacturing Process <input type="checkbox"/> Contractor for Testing <input type="checkbox"/> Label/Packaging <input type="checkbox"/> Company name change <input type="checkbox"/> Part number change <input type="checkbox"/> Supplier Recall, Field Action or Field Notice <input type="checkbox"/> DMR Update (Provide document ID(s) and revision): <input type="checkbox"/> Other:
<b>Proposed Effectivity (When)</b> <i>Proposed date or lot number of when change will be implemented:</i>	Click or tap here to enter text.
<b>Risk Assessment</b> <i>Provide a Rationale:</i>	Click or tap here to enter text.
<b>Qualifications / Validations Planned and/or Performed</b>	<input type="checkbox"/> Yes <i>(Provide description of activities and attach relevant documents including redlined SOPs or testing protocols and reports):</i>  <input type="checkbox"/> No <i>(Provide a Rationale):</i>

Additional Supplier Info (If applicable)			
<b>Inventory at Supplier</b> (Prior to Implementing Change)	Click or tap here to enter text.	<b>Quantity Available to Purchase</b> (Prior to Implementing Change)	Click or tap here to enter text.
<b>Date "Proposed / New" Parts Need to be Ordered:</b>		Click or tap here to enter text.	
<b>Date Shipments to TMC Will be Impacted:</b>		Click or tap here to enter text.	
<p><b>Please send the completed document as a Microsoft Word file to TMC representative</b>  <b>STOP: The remainder of the form is for TMC use.</b></p>			

**Section II – TMC Initial Review – For internal use at TMC only. Complete all fields or record "NA".**

This section will be completed by TMC Regulatory Affairs	
<b>Check if TMC Regulatory Assessment is Not Applicable</b>	<input type="checkbox"/> N/A (If N/A, leave section blank)
<b>US</b>	<input type="checkbox"/> No prior approval regulatory submission required <input type="checkbox"/> 30-Day Notice <input type="checkbox"/> Other:
<b>EU</b>	<input type="checkbox"/> No prior approval regulatory submission required <input type="checkbox"/> Substantial Change <input type="checkbox"/> Design Dossier/Technical Documentation Update <input type="checkbox"/> Other:
<b>Canada</b>	<input type="checkbox"/> No prior approval regulatory submission required <input type="checkbox"/> License Amendment <input type="checkbox"/> Other:
<b>International Regulatory</b>	Regulatory Notification/PCN Required: <input type="checkbox"/> No <input type="checkbox"/> Yes
<b>Comments</b> (Leave blank if not applicable):	

**This section will be completed by TMC Supplier Quality Engineering**

Supplier Number:	Click or tap here to enter text.	Impacted TMC Product(s) Family:	Click or tap here to enter text.	Impacted TMC Site(s):	Click or tap here to enter text.
<b>SCN Classification:</b>	<input type="checkbox"/> Change Type I		<input type="checkbox"/> Change Type II		
	<input type="checkbox"/> Change request denied/ canceled for the following reason:				
<b>Change Control Decision:</b>	Is a DHF update required? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A (if yes, Change Control is required)				
	Comments as applicable:				
	Is a DMR update required? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A (if yes, Change Control is required)				
	Comments as applicable:				
<b>SCN Determination:</b>	Is Change Control Required by Terumo?				
	<input type="checkbox"/> Yes (Provide Change Control Number):				
	<input type="checkbox"/> No (Provide Rationale):				
<input type="checkbox"/> SCN Canceled (Change request denied/canceled. Section III not required). <input type="checkbox"/> SCN Approved (Change Type I and Change Type II with no additional activities required. Section III not required). <input type="checkbox"/> SCN Plan Approved (Change Type I and Change Type II with additional activities required. Proceed to Section III for final approval).					

Function	Name Printed	Signature	Date
Add additional rows, as necessary, for approval signatures			

<b>Engineering (Required):</b>	Click or tap here to enter text.	Click or tap here to enter text.	Click or tap here to enter text.
<b>Supplier Quality (Required):</b>	Click or tap here to enter text.	Click or tap here to enter text.	Click or tap here to enter text.
<b>Regulatory Affairs:</b>	Click or tap here to enter text.	Click or tap here to enter text.	Click or tap here to enter text.
<b>Other (List Function):</b>	Click or tap here to enter text.	Click or tap here to enter text.	Click or tap here to enter text.

**Section III – Final Approval – This section will be completed by TMC Project Leader**

<b>Check if Section III is Not Applicable</b>	<input type="checkbox"/> N/A (If N/A leave section blank)
<b>Action Plan Results Summary:</b> <i>(Summarize qualification/validations performed by TMC and/or supplier)</i>	Click or tap here to enter text.
<b>Implementation Part and Lot Numbers:</b> <i>(List Part and Lot Numbers)</i>	Click or tap here to enter text.
<b>Final Team Review:</b>	<input type="checkbox"/> Change request is approved <input type="checkbox"/> Change request is denied/canceled for the following reason:

Function	Name Printed	Signature	Date
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*Add additional rows, as necessary, for approval signatures*

<b>Engineering (Required):</b>	Click or tap here to enter text.	Click or tap here to enter text.	Click or tap here to enter text.
<b>Supplier Quality (Required):</b>	Click or tap here to enter text.	Click or tap here to enter text.	Click or tap here to enter text.
<b>Regulatory Affairs:</b>	Click or tap here to enter text.	Click or tap here to enter text.	Click or tap here to enter text.
<b>Other (List Function):</b>	Click or tap here to enter text.	Click or tap here to enter text.	Click or tap here to enter text.

**Section IV – Verification Checklist (This section will be completed by the SQE Analyst or designee)**

Item	Document Requirements	Yes	N/A
1	All sections completed as required	<input type="checkbox"/>	<input type="checkbox"/>
2	Verify Section II and Section III approval signatures are complete (as required per QA295)	<input type="checkbox"/>	<input type="checkbox"/>
3	Verify approved SCN sent to supplier	<input type="checkbox"/>	<input type="checkbox"/>
4	<b>SQE Analyst or Designee:</b>	<b>Name Printed:</b>	Click or tap here to enter text.
		<b>Signature and Date:</b>	Click or tap here to enter text.