

**Section I – Supplier Change Information**

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)*

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.
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<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.
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<b>Supplier Change Order #, CAPA #, NC #, SCR #, Quality Plan #, etc.</b> <i>Provide Document Number:</i>	Click or tap here to enter text.
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<b>Related TMC Supplier Change Notification # (as applicable)</b> <i>Provide Document Number:</i>	Click or tap here to enter text.
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<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:
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<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.
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<b>Risk Assessment</b> <i>Provide a Rationale:</i>	Click or tap here to enter text.
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<b>Qualifications / Validations Planned and/or Performed:</b>	<input type="checkbox"/> Yes (Provide description of activities and attach relevant documents including redlined SOPs or testing protocols and reports):  <input type="checkbox"/> No (Provide a Rationale):
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**Please send the completed document as a Microsoft Word file to TMC representative**  
**STOP: The remainder of the form is for TMC use.**

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

**Inventory Impact Assessment**  
*(Completed by Production Planning/Purchasing)*

<b>Current Inventory On-hand</b> (Prior to Implementing Change):	Click or tap here to enter text.	<b>Current Inventory Run-Out Date</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>Estimated Change Implementation Date at Supplier:</b>	Click or tap here to enter text.

**SCN Classification**  
*(Completed by Supplier Quality Engineering – See 08-1TSOP-04 for additional guidance)*

<b>Supplier ID:</b>	Click or tap here to enter text.	<b>Impacted TMC Product(s) Family:</b>	Click or tap here to enter text.	<b>Impacted TMC Site(s):</b>	Click or tap here to enter text.
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**Change Assessment**  
*(This section will be completed by Supplier Quality Engineer and the cross-functional team)*

**Does the proposed change involve any modifications to the form fit or function of the finished device or the raw materials?**  Yes  No

Assessment: *(Consider the impact of the change on the form, fit, or function of the finished device, sub-assembly, or the raw material/component itself.)*

**Identify the impact on Design Control Documentation**  Yes  No

Assessment: *(Consider the impact on Design Inputs and Outputs, DHF, DMR, Design V&V, Risk Documents and summarize the activities required in the change plan. Itemize the activities required such as updates to Product Specifications, Drawings/MSS, BOM, Items Masters, Labeling/Artwork, manufacturing procedures, etc.)*

**Identify the impact on Biocompatibility or Bioburden**  Yes  No

Assessment: *(Consider the impact on biocompatibility in case of change to a raw material or its composition/formulation, changes to any mold release agent or chemicals that come into contact with the component, and impact on the bioburden levels in case of manufacturing location changes, cleanroom environment changes, etc.)*

**Does the proposed change impact current validated state of the suppliers or Terumo’s manufacturing process?**  Yes  No

Assessment: *(Identify the activities required at the supplier’s end and internal activities validation/qualification activities required at Terumo.)*

**Does the proposed change impact any existing incoming inspections, test methods, sample sizes?**  Yes  No

Assessment: *(Consider any impact to the existing test methods or sampling plans as a result of the proposed changes.)*

**Change Type I**  **Change Type II**

Change request denied/ canceled for the following reason:

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

**Check if TMC Regulatory Assessment is Not Applicable**  N/A (If N/A, leave section blank)

**US**  
 No prior approval regulatory submission required  
 30-Day Notice  
 Other:

**EU**  
 No prior approval regulatory submission required  
 Substantial Change  
 Design Dossier/Technical Documentation Update  
 Other:

**Canada**  
 No prior approval regulatory submission required  
 License Amendment  
 Other:

**International Regulatory** Regulatory Notification/PCN Required:  No  Yes

**Comments** (Leave blank if not applicable):

**SCN Determination:**  
 SCN Plan Approved (Change Type I and Change Type II with additional activities required. Proceed to Section III for final approval).  
 SCN Approved (Change Type I and Change Type II with no additional activities required. Section III not

	required). <input type="checkbox"/> SCN on hold (Change request on hold due to delayed implementation) <input type="checkbox"/> SCN Canceled (Change request denied/canceled. Section III not required).
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Function	Name Printed	Signature/Date
<i>Add additional rows, as necessary, for approval signatures</i>		
Engineering (Required):	Click or tap here to enter text.	See eDMS
Supplier Quality (Required):	Click or tap here to enter text.	
Regulatory Affairs (Required):	Click or tap here to enter text.	
Other (List Function):	Click or tap here to enter text.	

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

Check if Section III is Not Applicable:	<input type="checkbox"/> N/A (If N/A leave section blank)
Action Plan Results Summary: (Summarize qualification/validations performed by TMC and/or supplier)	<i>(Ensure all activities have been completed and objective evidences are included as attachments to the SCN on TMSWeb)</i>
Implementation Part and Lot Numbers: (List Part and Lot Numbers)	Click or tap here to enter text.
Final Team Review:	<input type="checkbox"/> Change request is approved <input type="checkbox"/> Change request is denied/canceled for the following reason:

Function	Name Printed	Signature/Date
<i>Add additional rows, as necessary, for approval signatures</i>		
Engineering (Required):	Click or tap here to enter text.	See eDMS
Supplier Quality (Required):	Click or tap here to enter text.	
Regulatory Affairs (Required):	Click or tap here to enter text.	
Other (List Function):	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 08-1TSOP-04)	<input type="checkbox"/>	<input type="checkbox"/>
3	Verify approved SCN sent to supplier	<input type="checkbox"/>	<input type="checkbox"/>
4	SQE Analyst or Designee:	Name Printed:	Click or tap here to enter text.
		Signature and Date:	See eDMS