

<p>1. Are all Verification/Validation Assessment questions listed below included as part of an approved project plan?</p> <p>If Yes is selected, document the plan or project number below and no further questions need to be answered.</p>	<p>Choose an item.</p>
<p>List plan or project number:</p>	
<p>Product Performance</p>	
<p>2. Does this change affect Product Performance (Customer Requirements, Products Requirements, Product Performance, etc)?</p>	<p>Choose an item.</p>
<p>3. Is a new part number (ZFIN/ZMOD) required? Refer to 87136 for interchangeability instructions.</p>	<p>Choose an item.</p>
<p>Enter new part number(s) or rationale for maintaining the existing number(s):</p>	
<p>4. Are current design verifications/validations/assessments/technical reports and/or risk assessments (e.g., UFMEA or DFMEA) affected?</p> <p>If Yes is selected, verification/validation is required. List applicable reference document(s) below.</p> <p>If No is selected, document rationale below.</p>	<p>Choose an item.</p>
<p>List applicable reference document(s) or rationale:</p>	
<p>Design/Packaging</p>	
<p>5. Does this change affect a new or updated design specification or a manufacturing process or procedure that is a control for the design (Materials, dimensions, tolerances, packaging, etc)?</p> <p>If No is selected, document rationale below.</p>	<p>Choose an item.</p>
<p>Rationale:</p>	
<p>6. Does this change affect a new or updated IFU and or Label?</p>	<p>Choose an item.</p>
<p>7. Is a new part number required? Determine per interchangeability procedure.</p> <p>If Yes is selected, enter new part number(s) below.</p> <p>If No is selected, document rationale below.</p>	<p>Choose an item.</p>
<p>Enter new part number(s) or rationale for not needing new number(s):</p>	

<p>8. Are current design verifications/validations/assessments/technical reports and/or risk assessments (e.g., UFMEA or DFMEA) affected?</p> <p>If Yes is selected, verification/validation is required. List applicable reference document(s) below.</p> <p>If No is selected, document rationale below.</p>	<p>Choose an item.</p>
<p>List applicable reference document(s) or rationale:</p>	
<p>Process</p>	
<p>9. Are current process verifications/validations/assessments/technical reports and/or risk assessments (e.g., PFMEAs) affected?</p> <p>If Yes is selected, validation is required. List applicable reference document(s) below.</p> <p>If No is selected, document rationale below.</p>	<p>Choose an item.</p>
<p>List applicable reference document(s) or rationale:</p>	
<p>10. Does this change affect a new or updated manufacturing process (MP change, operation sequence, etc.)?</p>	<p>Choose an item.</p>
<p>11. Does this change affect a new or updated manufacturing tooling (tooling change, calibration change, etc.)?</p>	<p>Choose an item.</p>
<p>12. Does change involve an equipment move, facility infrastructure change or process transfer?</p> <p>If Yes is selected, enter Quality Plan or Transfer # below.</p>	<p>Choose an item.</p>
<p>Quality Plan or Transfer #:</p>	
<p>Test/Inspection Methods</p>	
<p>13. Does this change affect a new or updated inspection method or test method?</p>	<p>Choose an item.</p>
<p>14. Are current process verifications/validations/assessments/technical reports and/or risk assessments (e.g., PFMEAs) affected??</p> <p>If Yes is selected, validation is required. List applicable reference document(s) below.</p> <p>If No is selected, document rationale below.</p>	<p>Choose an item.</p>
<p>List applicable reference document(s) or rationale:</p>	