

Title: **Supplier Change Control Form**

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|                                                                                                                                                                                                                                                                                                                                                                                             |                                                                                               |                                                                                                                                  |                               |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------|-------------------------------|
| <b>Change Ref No:</b>                                                                                                                                                                                                                                                                                                                                                                       |                                                                                               | PCN 21-03-06                                                                                                                     |                               |
| <small>PCN YY-MM-NN (For Waters use only)</small>                                                                                                                                                                                                                                                                                                                                           |                                                                                               |                                                                                                                                  |                               |
| <b>SECTION 1 – CHANGE REQUESTOR DETAILS</b> <i>(Supplier that submitting the change to Waters, which includes sub-level suppliers, contract manufacturers (CMs), 3PL, service suppliers. To be completed by Requestor)</i>                                                                                                                                                                  |                                                                                               |                                                                                                                                  |                               |
| <b>Supplier Company Name</b>                                                                                                                                                                                                                                                                                                                                                                | FLEXTRONICS                                                                                   |                                                                                                                                  |                               |
| <b>Requestor Name &amp; E-mail Address</b>                                                                                                                                                                                                                                                                                                                                                  | Joel Mamalateo Deduyo                                                                         |                                                                                                                                  |                               |
| <b>Is this change initiated from sub-level suppliers and submitting to Waters via Contract Manufacturer?</b>                                                                                                                                                                                                                                                                                |                                                                                               |                                                                                                                                  |                               |
| <input type="checkbox"/> Yes, please fill up the sub-level supplier detail in following column                                                                                                                                                                                                                                                                                              |                                                                                               | <input type="checkbox"/> No, please proceed to Section 2                                                                         |                               |
| <b>Sub-level Supplier Company Name</b>                                                                                                                                                                                                                                                                                                                                                      | N/A                                                                                           |                                                                                                                                  |                               |
| <b>Contact Person &amp; Email Address</b>                                                                                                                                                                                                                                                                                                                                                   | N/A                                                                                           |                                                                                                                                  |                               |
| <b>SECTION 2 – CHANGE DETAILS</b> <i>(To be completed by Requestor)</i>                                                                                                                                                                                                                                                                                                                     |                                                                                               |                                                                                                                                  |                               |
| <b>Description of Change</b> <i>(Provide a complete description of the change. Comparing the current situation with the new situation. )</i>                                                                                                                                                                                                                                                |                                                                                               |                                                                                                                                  |                               |
| <p>Current Practice:</p> <p>3x pages energy reading are present in DHR as follow :</p> <ul style="list-style-type: none"> <li>- Lambda1 Specification 178 to 188 nM</li> <li>- Lambda512 Specification 801.5 to 811.5 nM</li> <li>- Shunt / Cell energy 5ms Specification 80000 to 250000 counts.</li> </ul> <p>Propose Change:</p> <p>Remove 3x pages showing energy reading from DHR.</p> |                                                                                               |                                                                                                                                  |                               |
| <b>Reason for Change</b> <i>(Why is the change is necessary?)</i>                                                                                                                                                                                                                                                                                                                           |                                                                                               |                                                                                                                                  |                               |
| <p>The 3x energy readings below are redundant as it is not mention per TSP 735001613 PDA Detector Final Test</p> <ul style="list-style-type: none"> <li>- Lambda1 Specification 178 to 188 nM</li> <li>- Lambda512 Specification 801.5 to 811.5 nM</li> <li>- Shunt / Cell energy 5ms Specification 80000 to 250000 counts.</li> </ul>                                                      |                                                                                               |                                                                                                                                  |                               |
| <b>Any known constraints – e.g timing</b><br><i>(Any last time buy? Any impact to line down? Cross relevant option)</i>                                                                                                                                                                                                                                                                     | <input type="checkbox"/> Yes, please specify: _____<br><input checked="" type="checkbox"/> No |                                                                                                                                  |                               |
| <b>Target Implementation Date</b>                                                                                                                                                                                                                                                                                                                                                           | 1 April 2021                                                                                  | Is this date Proposed <input checked="" type="checkbox"/> or Required <input type="checkbox"/><br><i>(Cross relevant option)</i> |                               |
| <b>SECTION 3 – SCOPE OF CHANGE</b> <i>(Material information affected by the change, may attach list of part number where applicable. To be completed by Requestor)</i>                                                                                                                                                                                                                      |                                                                                               |                                                                                                                                  |                               |
| <b>Part No.</b>                                                                                                                                                                                                                                                                                                                                                                             | <b>Current Part Revision</b>                                                                  | <b>Description</b>                                                                                                               | <b>Waters Design (Yes/No)</b> |
| N/A                                                                                                                                                                                                                                                                                                                                                                                         | N/A                                                                                           | N/A                                                                                                                              | Choose an item.               |
| End of Data                                                                                                                                                                                                                                                                                                                                                                                 |                                                                                               |                                                                                                                                  | Choose an item.               |
|                                                                                                                                                                                                                                                                                                                                                                                             |                                                                                               |                                                                                                                                  | Choose an item.               |
|                                                                                                                                                                                                                                                                                                                                                                                             |                                                                                               |                                                                                                                                  | Choose an item.               |
|                                                                                                                                                                                                                                                                                                                                                                                             |                                                                                               |                                                                                                                                  | Choose an item.               |

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|------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------|-----------------------------------------------------------------------------|--------------------------------------------------------------------------------------------|
|                                                                                                                        |                                                                |                                                                             | Choose an item.                                                                            |
| <b>SECTION 4 – CHANGE ASSESSMENT</b> <i>(To evaluate the risk of the change request. To be completed by Requestor)</i> |                                                                |                                                                             |                                                                                            |
| <b>Change Category</b> <i>(Cross (X) relevant category)</i>                                                            |                                                                |                                                                             |                                                                                            |
| <b>High Risk</b><br><i>(Please complete Section 5 &amp; 6, then submit to Waters Procurement)</i>                      |                                                                |                                                                             | <b>Low Risk</b><br><i>(Please submit to Waters Procurement after completing Section 4)</i> |
| <input type="checkbox"/> Manufacturing Location Change (Critical Part)                                                 | <input type="checkbox"/> Supplier Name Change (New QMS)        | <input type="checkbox"/> Raw Material Change (Composition or Source)        | <input type="checkbox"/> Supplier Name Change (QMS Remains Valid)                          |
| <input type="checkbox"/> Design Change (Waters Design)                                                                 | <input type="checkbox"/> Design Change (Supplier Design)       | <input type="checkbox"/> Method/Equipment Change (Manufacturing or Testing) | <input type="checkbox"/> Supplier Location Change (Sales / Registered Office)              |
| <input type="checkbox"/> Subcontractor Change (Manufacturing or Testing)                                               | <input checked="" type="checkbox"/> Labelling/Packaging Change | <input type="checkbox"/> Process Change                                     | <input type="checkbox"/> Manufacturing Location Change (Standard Part)                     |
| <input type="checkbox"/> Other Changes, please state: _____                                                            |                                                                |                                                                             | <input checked="" type="checkbox"/> Other Changes, please state: DHR                       |
| Remarks (if any): 3x pages energy reading is available in Final Test Record                                            |                                                                |                                                                             |                                                                                            |

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## SECTION 5 – CHANGE IMPACT ASSESSMENT

*(This section only applicable to High Risk Change, for Low Risk Change please leave this section blank. To be completed by Requestor.)*

|                                                                                                                                                                  |     |                                                                                                                      |                                                                                                                                  |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----|----------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------|
| Does the change impact any Process? (Yes/No)<br><i>(Please declare process that affected by the change)</i>                                                      | Yes | Document Number or Process Step:<br><i>(Kindly attach relevant document)</i>                                         | N/A                                                                                                                              |
|                                                                                                                                                                  |     | If no, please justify:                                                                                               | N/A                                                                                                                              |
| Does the change impact a Validated Process/Equipment? (Yes/No)<br><i>(Please declare process/equipment that being validated internally or by Waters)</i>         | No  | Document Number or Process Step or Equipment Name:<br><i>(Kindly attach relevant document)</i>                       | N/A                                                                                                                              |
|                                                                                                                                                                  |     | If no, please justify:                                                                                               | The removal of 3x pages on the Devices History Record of Validated Process/Equipment does not impact the form-fit-function.      |
| Does the change impact any IVD Instrument/convertible IVD Instrument? (Yes/No)<br><i>(Please declare all affected IVD Instrument/convertible IVD Instrument)</i> | No  | Affected IVD / convertible IVD Instrument Model Number:                                                              | N/A                                                                                                                              |
|                                                                                                                                                                  |     | If Yes, please provide the Risk Assessment File / PFMEA Document Number:<br><i>(Kindly attach relevant document)</i> | The TSP 735001613 does not cover any IVD Instrument / convertible IVD instrument thus no impact to any IVD product               |
| Does the change impact a specification/drawing? (Yes/No)<br><i>(This includes Waters and Suppliers specification and drawing)</i>                                | No  | Document Number:<br><i>(Kindly attach relevant document)</i>                                                         | TSP 735001613 Rev AC                                                                                                             |
|                                                                                                                                                                  |     | If no, please justify:                                                                                               | The TSP 735001613 does not mentioned to perform this activity on the section mentioned thus no impact to specification / drawing |

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**\*\* For SECTION 6 & 8A only applicable to High Risk Change, for Low Risk Change you may leave both section blank if there is no action required to implement the change.**

| SECTION 6 – CHANGE CONTROL PLAN <i>(Propose action plan in order to implement the change, may attach list of action where applicable. To be completed by Requestor.)</i> |                     |                               |                               | SECTION 8A CHANGE CLOSURE <i>(For Waters use only)</i> |                  |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------|-------------------------------|-------------------------------|--------------------------------------------------------|------------------|
| No.                                                                                                                                                                      | Action Description  | Owner<br>(CM/Supplier/Waters) | Target Completion<br>Date     | Evidence<br>Attached<br>(Yes/No)                       | Review By / Date |
| 1                                                                                                                                                                        | Remove the 3x pages | Joel                          | 21 April 2021                 | Choose an item.                                        |                  |
| 2                                                                                                                                                                        | End of Data         |                               | Click or tap to enter a date. | Choose an item.                                        |                  |
| 3                                                                                                                                                                        |                     |                               | Click or tap to enter a date. | Choose an item.                                        |                  |
| 4                                                                                                                                                                        |                     |                               | Click or tap to enter a date. | Choose an item.                                        |                  |

**Submitted by**  
*(if this change originated from sub-level suppliers and submitted to Waters via CM, only CM is required to sign off)*

| Requestor Name        | Signature                                                                         | Date          |
|-----------------------|-----------------------------------------------------------------------------------|---------------|
| Joel Mamalateo Deduyo |  | 10 March 2021 |

**SECTION 7 – CHANGE CONTROL PLAN APPROVAL** *(This section is required only when Section 6 is filled up. For Waters use only. Refer to WPPL-SP-09 for required approvals.)*

| Department            | Name | Signature | Date                          |
|-----------------------|------|-----------|-------------------------------|
| Procurement           |      |           | Click or tap to enter a date. |
| Quality               |      |           | Click or tap to enter a date. |
| Manufacturing         |      |           | Click or tap to enter a date. |
| Supply & Distribution |      |           | Click or tap to enter a date. |
| Product Planning      |      |           | Click or tap to enter a date. |
| Test                  |      |           | Click or tap to enter a date. |
| Other                 |      |           | Click or tap to enter a date. |
| Remarks (if any)      |      |           |                               |

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| SECTION 8B – CHANGE CLOSURE <i>(Change Closure Result. Cross relevant option. For Waters use only)</i>                                                            |      |                                                              |                               |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------|------|--------------------------------------------------------------|-------------------------------|
| <input type="checkbox"/> Change Request Approved. Authorization can now be given to implement the change(s).<br><input type="checkbox"/> Change Request Rejected. |      |                                                              |                               |
| Department                                                                                                                                                        | Name | Signature                                                    | Date                          |
| Procurement                                                                                                                                                       |      |                                                              | Click or tap to enter a date. |
| Quality                                                                                                                                                           |      |                                                              | Click or tap to enter a date. |
| Remarks (if any)                                                                                                                                                  |      |                                                              |                               |
|                                                                                                                                                                   |      | Engineering Change Order Number<br><i>(where applicable)</i> |                               |