

Title: Supplier Change Control Form

Document No: 730006720

Version No: 01

Page 1 of 5

Change Ref No: <i>PCN YY-MM-NN (For Waters use only)</i>		PCN 21-03-06
SECTION 1 – CHANGE REQUESTOR DETAILS <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>		
Supplier Company Name	FLEXTRONICS	
Requestor Name & E-mail Address	Joel Mamalateo Deduyo	
Is this change initiated from sub-level suppliers and submitting to Waters via Contract Manufacturer?		
☐ Yes, please fill up the sub-level supplier detail in following column		☐ No, please proceed to Section 2
Sub-level Supplier Company Name	N/A	
Contact Person & Email Address	N/A	

SECTION 2 – CHANGE DETAILS <i>(To be completed by Requestor)</i>		
Description of Change <i>(Provide a complete description of the change. Comparing the current situation with the new situation.)</i>		
Current Practice: 3x pages energy reading are present in DHR as follow : - Lambda1 Specification 178 to 188 nM - Lambda512 Specification 801.5 to 811.5 nM - Shunt / Cell energy 5ms Specification 80000 to 250000 counts. Propose Change: Remove 3x pages showing energy reading from DHR.		
Reason for Change <i>(Why is the change is necessary?)</i>		
The 3x energy readings below are redundant as it is not mention per TSP 735001613 PDA Detector Final Test - Lambda1 Specification 178 to 188 nM - Lambda512 Specification 801.5 to 811.5 nM - Shunt / Cell energy 5ms Specification 80000 to 250000 counts.		
Any known constraints – e.g timing <i>(Any last time buy? Any impact to line down? Cross relevant option)</i>	☐ Yes, please specify: _____ ☒ No	
Target Implementation Date	1 April 2021	Is this date Proposed ☒ or Required ☐ <i>(Cross relevant option)</i>

SECTION 3 – SCOPE OF CHANGE <i>(Material information affected by the change, may attach list of part number where applicable. To be completed by Requestor)</i>			
Part No.	Current Part Revision	Description	Waters Design (Yes/No)
N/A	N/A	N/A	Choose an item.
End of Data			Choose an item.
			Choose an item.
			Choose an item.
			Choose an item.

Title: Supplier Change Control Form

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

Title: **Supplier Change Control Form**

Document No: 730006720

Version No: 01

Page 3 of 5

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) <i>(Please declare process that affected by the change)</i>	Yes	Document Number or Process Step: <i>(Kindly attach relevant document)</i>	N/A
		If no, please justify:	N/A
Does the change impact a Validated Process/Equipment? (Yes/No) <i>(Please declare process/equipment that being validated internally or by Waters)</i>	No	Document Number or Process Step or Equipment Name: <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) <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: <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) <i>(This includes Waters and Suppliers specification and drawing)</i>	No	Document Number: <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

Title: **Supplier Change Control Form**

Document No: 730006720

Version No: 01

Page 4 of 5

**** 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 (CM/Supplier/Waters)	Target Completion Date	Evidence Attached (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	Luo HuaZhen		07 Apr 2021 Click or tap to enter a date.
Other			Click or tap to enter a date.
Remarks (if any)			

Title: **Supplier Change Control Form**

Document No: 730006720

Version No: 01

Page 5 of 5

SECTION 8B – CHANGE CLOSURE <i>(Change Closure Result. Cross relevant option. For Waters use only)</i>			
☐ Change Request Approved. Authorization can now be given to implement the change(s). ☐ 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 <i>(where applicable)</i>	