

Title: Temporary Manufacturing Deviation Form

Document No: 730002479

Version No: 05

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Originator: Charlie Bergeron		Date: 04-Apr-2018		TMD #:		v 00	
Lab Office: AKG		Notify: Keith Lavallee & Edwin Koh		Requester: Jaaffar Ismail			
P/N(s): 186015080		P/N ACQUITY UPLC H-Class QSM PLUS Desc.:					
Expiration Type: ☐ Date <i>or</i> ☒ Qty/Lot		Expiration Date: N/A		Expiration Detail: 3 instruments			
Risk Assessor: Charlie Bergeron		TMD Category: Pilot Run					
Reason for Deviation (<i>describe why deviation is needed</i>): The current 186015080 ACQUITY UPLC H-Class QSM PLUS BOM, genealogy and ASP reflects the conversion of 186015018 ACQUITY UPLC QSM, not a complete build from the sheet metal up. Also the current test equipment TE82943-XX and TSP 735002155 at Contract Mfg. Flex does not include the 186015080 model. This deviation will allow for the (3) ACQUITY UPLC H-Class QSM PLUS consignment builds at Flex using released and unreleased documentation provided by Milford NPI and to test instruments as 186015018 ACQUITY UPLC QSM modifying the test record as described in the Deviation Description section until Milford Test Engineering can upgrade the test program, perform qualification and revise the test procedure.							
Deviation Description (<i>what is deviating and scope, e.g., time/quantity limits, where-used, products affected, potential cost</i>): This deviation is for (3) consignment build 186015080 ACQUITY UPLC H-Class QSM PLUS instruments at Flex to be delivered to Milford NPI for inspection and re-test as detailed below : 1) Use released and unreleased documentation as provided by Milford NPI. This includes a 279003870 ASSY,QSM PLUS build level with the new components for the PLUS model. 2) Create a genealogy record using the Flex internal process for those items in the 279003870 ASP that have the "scan" icon. 3) Test instruments using TSP 735002155 as a 186015018 ACQUITY UPLC QSM instead of 186015080 ACQUITY UPLC H-Class QSM PLUS. Upon completion of final test, draw a single line through the part number and serial number, replacing it with the 186015080 ACQUITY UPLC H-Class QSM PLUS part number and serial number. Record the TMD in the test report. Initial & date the changes. 4) Complete the 186015080 ACQUITY UPLC H-Class QSM PLUS shipping level per the 186015080 ASP. Place a copy of the test record and genealogy in the shipping box. 5) Ship to Milford NPI for inspection and re-test.							
ECR/ECO Number(s): N/A							
APPROVALS							
Role	Req?	Printed Name	Signature			Date	
Engineering	X	Jim Usowicz	REFER TO SAP FOR SIGNATURE			DATE	
Operations	X	Andrew Day	REFER TO SAP FOR SIGNATURE			DATE	
Quality	X	Denise Soter	REFER TO SAP FOR SIGNATURE			DATE	
Other	☐	N/A	N/A			N/A	

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Risk Assessment/Justification <i>(assess impact to product, process, compliance; describe why deviation is acceptable)</i> The severity of negative impact of this deviation is Minor because instruments will be inspected and re-tested on validated test equipment to verify that instruments meet all specifications in Milford NPI prior to release for distribution. The likelihood of negative impact from this deviation is Rare because the current test controls will identify a defect or failure. Therefore the overall risk is Low.			
Compliance Engineering Consulted?	No ☒	Yes ☐	Name: N/A
Implementation Plan <i>(describe who, when, how of implementation):</i> For Singapore Personnel: This TMD is to be implemented as detailed in the Deviation Description by the contract manufacturer Flex for the consignment build: - Build (3) 186015080 ACQUITY UPLC H-Class QSM PLUS instruments using the documentation provided by Milford NPI. - Perform Final Test for P/N 186015018 (H-Class QSM) using TSP 735002155. Record part number 186015080, the serial number and the TMD # on the Final Test Record. - Place copy of test record and genealogy in the instrument shipping box. - Ship the Milford attention to Keith Lavallee. For Milford NPI Personnel: - Inspect and re-test consignment instruments using TSP 735002155 for the 186015080 ACQUITY UPLC H-Class QSM PLUS model on validated test equipment. Record the TMD# on the test record. - Create a secondary DHR for the instruments according to 730000709 requirements by using the genealogy shipped with the unit. A copy of the Milford Final Test Records will be attached to this TMD prior to closure.			

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