



SKW-ENG4034-00
Validation Change Control Assessment Form

Rev: A

Document Title: Validation Change Control Assessment For Decommissioning of Acquity Solvent Delivery System Final Tester TE82943-17 and 18	Engineering Change No.: NA	Document #: WAT-RW-SKI06891	Organization: Kallang
Revision: A	Document Owner: Joel Mamalateo Deduyo	Customer: Waters Corporation	Effective Date: FlexQ – On File
Applicable To:	☒ ALL CUSTOMER ☒ PLS SPECIFY: 186015001, 186015018, 186015080		

APPROVALS			
NAME	TITLE	FUNCTION	DATE
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REVIEW / APPROVAL BY CUSTOMER			
NAME	TITLE	SIGNATURE	DATE
Luo HuaZhen	Senior Test Engineer		06 Jul 2021

REVISION HISTORY				
REV.	ECN	DESCRIPTION OF CHANGE	ORIGINATOR	RELEASE DATE
A	NA	Decommission of Acquity Solvent Delivery System Final Tester TE82943-17 and 18 which the fixture will be decommissioned and removed from Production use and return to WPPL.	Joel Mamalateo Deduyo	FlexQ – On File

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(1) System Information			
☐ Process	☐ Software	☐ Facilities/Utility	☒ Equipment
(2) System/Equipment Name: Acquity Solvent Delivery System Final Tester			
(3) Serial Number and/or Identification Number: TE82943-17 and 18			
(4) Change Information Description of Change: Decommission of Acquity Solvent Delivery System Final Tester TE82943-17 and 18 which the Final Tester will be retired and removed from production use. Decommission of the Acquity Solvent Delivery System Final Tester TE82943-17 and 18 include the below activities: • Quarantine the fixture with proper tag indicate as Acquity Solvent Delivery System Final Tester TE82943-17 and 18 is not for production used. • Review Calibration records of calibrated equipment of the Tester. Remove the calibrated equipment from the Calibration System. • Review the Preventive Maintenance records to ensure no impact to product. Remove the Tester from the Preventive Maintenance program. • Upon the approval of the Validation Report IQ For End Of Life Of Acquity Solvent Delivery System Final Tester TE82943-17 and 18 that justify and state that the Tester is formally decommissioned, the Tester will be removed from production floor.			
(5) Reason For Change: ECO? ☐ Yes ☒ No If yes, please provide ECO #: <u>NA</u>			
(6) Description of Reason For Change: Acquity Solvent Delivery System Final Tester TE82943-17 and 18 will be retired as the present tester capacity is sufficient for the demand			
(7) Impact Of Change (Reference to System/Hardware/Software/Document and others if applicable): Acquity Solvent Delivery System Final Tester TE82943-17 and 18 is to be decommissioned as present tester capacity is sufficient to as per demand . Decommissioned tester shall be return to WPPL. This is a standalone final tester which has no association with any validated fixture or any other tester currently active at production. Hence, no impact of change will occur.			
(8) Required Activities To Verify A Successful Change Method of Change: Successfully complete the below: a) Review preventive maintenance records (include any downtime records) of the Tester to ensure no impact to the product. Verify the removal of the Tester from the Preventive Maintenance program. b) Review Calibration records of the calibrated equipment of the Tester. Verify the removal of the ancillary equipment from the Calibration System. c) Complete a Validation Report with records to justify and formally decommission the Tester upon approval. This report will indicate the obsoleting of the previous IQ and OQ Validation reports with reference to the respective Protocols too. Validation Master Plan (VMP) will be updated to reflect the change status.			
(9) (IQ/OQ/PQ As Applicable) Testing and Documentation Requirements: IQ Validation Report is required to justify and state that the Tester is formally decommissioned. Successful approval of the report shall qualify the changes. Obsolete validation documents in relation with present tester a. Installation Qualification Report For the Acquity SDS Final Test System TE82943-17 – WAT-RW-SKI04562 Rev F b. Installation Qualification Report For the Acquity SDS Final Test System TE82943-18 -WAT-RW-SKI04563 Rev F			
(10) The Method To Recover To The Validated State If The Change Is Not Successful: NA			