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Document #: TE0084040-1 -13APR20-VAF	SAP #: TE008404001

VALIDATION ASSESSMENT
For the METERING SYRINGE VALVE LEAK TEST SYSTEM, TE0084040-1

PREPARED BY

Name	Role	Signature	Date
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REVIEWED BY

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APPROVED BY

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The "Prepared By" signature denotes that this document accurately describes the planned Process Validation activities.

The "Reviewed By" signature denotes agreement with the details of the planned testing and/or deliverables to be performed in order to qualify the METERING SYRINGE VALVE LEAK TEST SYSTEM, TE0084040-1.

The "Approved By" signature denotes that this document has been reviewed and approved for overall quality and completeness.

1. PURPOSE

The purpose of the Validation Assessment Form (VAF) is to document the assessment of an engineering change to the released METERING SYRINGE VALVE LEAK TEST SYSTEM (TE0084040-1). This document shall also define the deliverable(s) required to maintain the equipment qualification, based on the engineering change. Qualification of the equipment shall ensure that it functions within its specifications.

2. BACKGROUND

This equipment measures the leak rate of all three port to port fluidic paths in the Metering Syringe Valve Assy. 289010714 and 289012763. After test, this assembly is installed into all sample manager products and shipped as spares.

3. DESCRIPTION OF CHANGE

3.1. This equipment is being shipped from Waters Milford Site to Waters Singapore contract manufacturing site Venture as part of MSV product transfer. This system will be delivered, installed and qualified at Venture as per plan.

4. RISK ASSESSMENT**4.1. High Risk Assessment**

Please check the appropriate boxes below to determine the high risk assessed qualification or requalification requirements:

4.1.1. Specification	No	Yes
Is the change a test specification value being modified and/or added?	☒	☐

4.1.2. Software/Firmware	No	Yes
Is the change a software modification that affects the way the system controls, and/or measures a test specification and/or PSC result?	☒	☐
Is the change due to firmware downloaded to the UUT by a test system?	☒	☐
Is the change a flash file update?	☒	☐
Is it a change to an existing, or the addition of a new, PCB Test Sequence?	☒	☐

4.1.3. Hardware (Mechanical, Electrical, Pneumatic, Hydraulic, etc.)	No	Yes
Is the change a mechanical, electrical, pneumatic, and/or hydraulic modification that alters the way the system controls, and/or measures a test specification and/or PSC result?	☒	☐

4.1.4. Equipment/Process Moves	No	Yes
Is the change a move of the equipment, test method or process, to a different facility?	☐	☒

4.2. Medium Risk Assessment

Please check the appropriate boxes below to determine the medium risk assessed qualification or requalification requirements:

4.2.1. Replacement of Non-Identical	No	Yes
Is the change due to a replacement of a system component with a non-identical equivalent?	☒	☐

4.2.2. Computer Related or Replacement of Custom PCBs	No	Yes
Is the change an update to the PC operating system?	☒	☐
Is the change a computer or printed circuit board replacement?	☒	☐

4.2.3. Software/Firmware	No	Yes
Is the change a minor software bug fix or a minor improvement (i.e. a part number add)?	☒	☐
Is the change a test system instrument firmware update (i.e. update to a stack component)?	☒	☐

4.2.4. Equipment/Process Moves	No	Yes
Is the change a move of the equipment, test method or process, within the Milford site?	☒	☐

4.3. This change results in a High Risk Assessment and the associated qualification requirements, as detailed in Section 6.0.

5. **HAZARD ASSESSMENT:**

There are no hazards potentially introduced to the environment, operator, assembler, service technician or end user due to this change.

6. **VERIFICATION, QUALIFICATION AND/OR VALIDATION:**

6.1. Equipment Design Verification (EDV)	No	Yes
Based on the Risk Assessment, does an EDV Protocol need to be created or revised due to this change?	☒	☐
Based on the Risk Assessment, does an EDV Protocol need to be executed due to this change? (Justify partial execution in the Comments/Justification section below.)	☒	☐
Comments/Justification An EDV is not required because this change does not affect the way system controls or measures a specification or PSC result.		

6.2. Installation Qualification (IQ)	No	Yes
Based on the Risk Assessment, does an IQ Protocol need to be executed due to this change? (Justify partial execution in the Comments/Justification section below.)	☐	☒
Comments/Justification A full Installation Qualification will be performed using the Installation Qualification Protocol 730004135 for this system located at Waters Singapore contract manufacturing site Venture.		

6.3. Test Method Validation (TMV)	No	Yes
Based on the Risk Assessment, does a TMV need to be executed due to this change? (Justify partial execution in the Comments/Justification section below.)	☒	☐
Comments/Justification A TMV is not required because there is no change to measurement equipment.		

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6.4. Operational Qualification (OQ)	No	Yes
Based on the Risk Assessment, does an OQ Protocol need to be created or revised due to this change?	☒	☐
Based on the Risk Assessment, does an OQ need to be executed due to this change? (Justify partial execution in the Comments/Justification section below.)	☒	☐
Comments/Justification An OQ is not required because 100% of critical to quality attributes are verified.		

6.5. Performance Qualification (PQ)	No	Yes
Based on the Risk Assessment, does a PQ Protocol need to be created or revised due to this change?	☒	☐
Based on the Risk Assessment, does a PQ need to be executed due to this change? (Justify partial execution in the Comments/Justification section below.)	☒	☐
Comments/Justification A PQ is not required because 100% of critical to quality attributes are verified.		

6.6. Electromagnetic Interference (EMI) Assessment:

This change only affects test equipment; therefore, there is no impact to product EMI.

7. IMPLEMENTATION ASSESSMENT:

- There is no impact to documentation or facilities/utilities. This system TE0084040-1 will be added to the Calibration/Preventative Maintenance database at Venture.
- There is no impact to any other qualified, verified, or validated Process, Test Method, or Equipment.
- The impact on production schedules will be low.
- The system will be installed, and an installation qualification will be executed by Venture personnel with guidance from Test Engineering and Validation Engineering as appropriate.
- A self-reading training is required by Venture personnel with guidance from Testing Engineering and Validation Engineering as appropriate.