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| <br><small>THE SCIENCE OF WHAT'S POSSIBLE.™</small> | Validation Assessment Form |
| Document #: TE0084040-2 -14APR20-VAF                                                                                                | SAP #: TE008404002         |

**VALIDATION ASSESSMENT**  
For the METERING SYRINGE VALVE LEAK TEST SYSTEM, TE0084040-2

**PREPARED BY**

| Name         | Role                 | Signature | Date |
|--------------|----------------------|-----------|------|
| Luo Hua Zhen | Senior Test Engineer |           |      |

**REVIEWED BY**

| Name          | Role                    | Signature | Date |
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| Richard Davis | Principal Test Engineer |           |      |

**APPROVED BY**

| Name         | Role                             | Signature | Date |
|--------------|----------------------------------|-----------|------|
| Kah Chin Tan | Senior Quality Assurance Manager |           |      |

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, TE0084040-2.

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 (TE0084040-2). 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:

| <b>4.1.1. Specification</b>                                           | <b>No</b>                           | <b>Yes</b>               |
|-----------------------------------------------------------------------|-------------------------------------|--------------------------|
| Is the change a test specification value being modified and/or added? | <input checked="" type="checkbox"/> | <input type="checkbox"/> |

| <b>4.1.2. Software/Firmware</b>                                                                                                         | <b>No</b>                           | <b>Yes</b>               |
|-----------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------|--------------------------|
| Is the change a software modification that affects the way the system controls, and/or measures a test specification and/or PSC result? | <input checked="" type="checkbox"/> | <input type="checkbox"/> |
| Is the change due to firmware downloaded to the UUT by a test system?                                                                   | <input checked="" type="checkbox"/> | <input type="checkbox"/> |
| Is the change a flash file update?                                                                                                      | <input checked="" type="checkbox"/> | <input type="checkbox"/> |
| Is it a change to an existing, or the addition of a new, PCB Test Sequence?                                                             | <input checked="" type="checkbox"/> | <input type="checkbox"/> |

| <b>4.1.3. Hardware (Mechanical, Electrical, Pneumatic, Hydraulic, etc.)</b>                                                                                                       | <b>No</b>                           | <b>Yes</b>               |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------|--------------------------|
| 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? | <input checked="" type="checkbox"/> | <input type="checkbox"/> |

| <b>4.1.4. Equipment/Process Moves</b>                                                   | <b>No</b>                | <b>Yes</b>                          |
|-----------------------------------------------------------------------------------------|--------------------------|-------------------------------------|
| Is the change a move of the equipment, test method or process, to a different facility? | <input type="checkbox"/> | <input checked="" type="checkbox"/> |

**4.2. Medium Risk Assessment**

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

| <b>4.2.1. Replacement of Non-Identical</b>                                                | <b>No</b>                           | <b>Yes</b>               |
|-------------------------------------------------------------------------------------------|-------------------------------------|--------------------------|
| Is the change due to a replacement of a system component with a non-identical equivalent? | <input checked="" type="checkbox"/> | <input type="checkbox"/> |

| 4.2.2. Computer Related or Replacement of Custom PCBs          | No                                  | Yes                      |
|----------------------------------------------------------------|-------------------------------------|--------------------------|
| Is the change an update to the PC operating system?            | <input checked="" type="checkbox"/> | <input type="checkbox"/> |
| Is the change a computer or printed circuit board replacement? | <input checked="" type="checkbox"/> | <input type="checkbox"/> |

| 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)?    | <input checked="" type="checkbox"/> | <input type="checkbox"/> |
| Is the change a test system instrument firmware update (i.e. update to a stack component)? | <input checked="" type="checkbox"/> | <input type="checkbox"/> |

| 4.2.4. Equipment/Process Moves                                                          | No                                  | Yes                      |
|-----------------------------------------------------------------------------------------|-------------------------------------|--------------------------|
| Is the change a move of the equipment, test method or process, within the Milford site? | <input checked="" type="checkbox"/> | <input type="checkbox"/> |

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?                                                                  | <input checked="" type="checkbox"/> | <input type="checkbox"/> |
| 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.)   | <input checked="" type="checkbox"/> | <input type="checkbox"/> |
| <b>Comments/Justification</b><br><b>An EDV is not required because this change does not affect the way system controls or measures a specification or PSC result.</b> |                                     |                          |

| 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.)                                                                   | <input type="checkbox"/> | <input checked="" type="checkbox"/> |
| <b>Comments/Justification</b><br><b>A full Installation Qualification will be performed using the Installation Qualification Protocol 730004135 for this system located at Waters Singapore contract manufacturing site Venture.</b> |                          |                                     |

| 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.) | <input checked="" type="checkbox"/> | <input type="checkbox"/> |
| <b>Comments/Justification</b><br><b>A TMV is not required because there is no change to measurement equipment.</b>                                        |                                     |                          |

| 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?                                                       | <input checked="" type="checkbox"/> | <input type="checkbox"/> |
| 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.) | <input checked="" type="checkbox"/> | <input type="checkbox"/> |
| <b>Comments/Justification</b><br><b>An OQ is not required because 100% of critical to quality attributes are verified.</b>                                |                                     |                          |

| 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?                                                       | <input checked="" type="checkbox"/> | <input type="checkbox"/> |
| 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.) | <input checked="" type="checkbox"/> | <input type="checkbox"/> |
| <b>Comments/Justification</b><br><b>A PQ is not required because 100% of critical to quality attributes are verified.</b>                                |                                     |                          |

**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 TE0084040-2 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.