

|                                                                  |  |                                          |                            |
|------------------------------------------------------------------|--|------------------------------------------|----------------------------|
| <b>Waters</b><br><small>THE SCIENCE OF WHAT'S POSSIBLE.™</small> |  | <b>Installation Qualification Report</b> |                            |
| <b>Report No: TE82943-13-IQR</b>                                 |  | <b>Iteration No: 01</b>                  | <b>SAP No: TE0082943QX</b> |

**INSTALLATION QUALIFICATION REPORT**  
 For the Acquity SDS Automated Test System (TE82943-13)

**PREPARED BY**

| Name         | Role                   | Signature                                                                          | Date        |
|--------------|------------------------|------------------------------------------------------------------------------------|-------------|
| Chan Yee Hwa | Manufacturing Engineer |  | 25 APR 2018 |

**REVIEWED BY**

| Name        | Role                     | Signature | Date |
|-------------|--------------------------|-----------|------|
| Emma Pierce | Test Validation Engineer |           |      |
| Ed Jackson  | Principal Test Engineer  |           |      |

**APPROVED BY**

| Name          | Role                               | Signature | Date |
|---------------|------------------------------------|-----------|------|
| Andre Kopoyan | Senior Operations Quality Engineer |           |      |

The "Prepared By" signature denotes that this document accurately describes the qualification activities.

The "Reviewed By" signature[s] denotes agreement with the description of the qualification activities.

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

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**REVISION HISTORY**

| Iteration | Author        | Summary of Change           |
|-----------|---------------|-----------------------------|
| 00        | Siew Yee Yeap | First document for approval |

|                                                   |                        |                                                |                     |
|---------------------------------------------------|------------------------|------------------------------------------------|---------------------|
| <b>Waters</b><br>THE SCIENCE OF WHAT'S POSSIBLE.™ |                        | <b>Installation Qualification Report</b>       |                     |
| Report No: TE82943-13-IQR                         |                        | Iteration No: 01                               | SAP No: TE0082943QX |
| 01                                                | <del>Emme Pierce</del> | Part number add, firmware and software updates |                     |

Chan Yee Hwa

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|                                                                  |                                          |                            |  |
|------------------------------------------------------------------|------------------------------------------|----------------------------|--|
| <b>Waters</b><br><small>THE SCIENCE OF WHAT'S POSSIBLE.™</small> | <b>Installation Qualification Report</b> |                            |  |
| <b>Report No: TE82943-13-IQR</b>                                 | <b>Iteration No: 01</b>                  | <b>SAP No: TE0082943QX</b> |  |

## 1.0 Purpose

The Acquity SDS Automated Test System (TE82943-13) is located at the WPPL Flextronics Contract Manufacturer Site in Singapore. The test station is used to perform the final functional test of the following part numbers: 186015000, 186015001, 186015018, 186015041, 186015080, 186015081, 186015082, 186015083, 18615084, and N2971030. This system has two software versions installed to test QSM and BSM products. In the final test, the UUT is connected to the test station and the electrical, mechanical, and fluidic performance of the unit are tested.

This Installation Qualification is being performed as required by ~~TE82943-28MAR2018-VAF~~, which can be found in the TE0082943QX directory of SAP.

TE82943-28MAR2018-VAF

## 2.0 Scope of Report

This Installation Qualification Report details the qualification activities undertaken for the Acquity SDS Automated Test System (TE82943-13) based on the requirements of the Installation Qualification Procedure 730004135, Ver. 00.

This Installation Qualification Report defines the documents used to qualify the Acquity SDS Automated Test System (TE82943-13).

## 3.0 Summary of Results - Statement of Fitness for Intended Use

The Acquity SDS Automated Test System was tested in accordance with the Installation Qualification Procedure 730004135, Ver. 00. All required Test Scripts were performed and all objective evidence requirements have been met.

Waters now has the necessary documentation in place to ensure that the Acquity SDS Automated Test System complies with Waters' requirements, the latest relevant quality system regulations, and cGMP practices.

Following the approval of this Qualification Report, the Acquity SDS Automated Test System (TE82943-13) can be considered fully qualified and fit for intended use.

## 4.0 Glossary

The following definitions are used in this document:

| Term  | Explanation                         |
|-------|-------------------------------------|
| %     | Percent                             |
| §     | Section                             |
| BOM   | Bill of Materials                   |
| BSM   | Binary Solvent Manager              |
| CAL   | Calibration                         |
| cGMP  | Current Good Manufacturing Practice |
| CTQ   | Critical to Quality                 |
| ECR   | Engineering Change Request          |
| EDV   | Equipment Design Verification       |
| FW    | Firmware                            |
| ID    | Identification                      |
| IPA   | Isopropanol                         |
| IQ(R) | Installation Qualification (Report) |

|                                                                 |  |                                          |                            |
|-----------------------------------------------------------------|--|------------------------------------------|----------------------------|
| <b>Waters</b><br><small>THE SCIENCE OF WHAT'S POSSIBLE™</small> |  | <b>Installation Qualification Report</b> |                            |
| <b>Report No: TE82943-13-IQR</b>                                |  | <b>Iteration No: 01</b>                  | <b>SAP No: TE0082943QX</b> |

| Term           | Explanation                                                      |
|----------------|------------------------------------------------------------------|
| LED            | Light Emitting Diode                                             |
| LSL            | Lower Specification Limit                                        |
| MeOH           | Methanol                                                         |
| mL/min         | Milliliters per Minute                                           |
| N/A            | Not Applicable                                                   |
| nL/min         | Nanoliters per Minute                                            |
| <del>NPI</del> | <del>New Product Introduction</del> <i>remove this line item</i> |
| P/N            | Part Number                                                      |
| PSI(G/min)     | Pounds per Square Inch (Gauge per Minute)                        |
| QSM            | Quaternary Solvent Manager                                       |
| SAP            | Enterprise Resource Planning Software                            |
| SDS            | Solvent Delivery System                                          |
| TMD            | Temporary Manufacturing Deviation                                |
| TSP            | Test Specification and Procedure                                 |
| uL (uL)        | Microliters                                                      |
| UPLC           | Ultra Performance Liquid Chromatography                          |
| USL            | Upper Specification Limit                                        |
| UUT            | Unit Under Test                                                  |
| VAF            | Validation Assessment Form                                       |
| VDC            | Volts Direct Current                                             |
| WPPL           | Waters Pacific Private Limited                                   |

## 5.0 Training

The operator of the Acquity SDS Automated Test System (TE82943-13) was trained according to the Acquity BSM Pump Automated Test Procedure 735002010, Rev. L, Ver. 10, the Acquity QSM Final Instrument Test Procedure 735002155, Rev. H, Ver. 07. The ~~executors~~ of this qualification were trained according to the Installation Qualification Procedure 730004135, Ver. 00. Operator and executor training records are provided as Attachment 7.1 and 7.2, respectively.

*executor - singular*

|                                                   |                                          |                  |                     |
|---------------------------------------------------|------------------------------------------|------------------|---------------------|
| <b>Waters</b><br>THE SCIENCE OF WHAT'S POSSIBLE.™ | <b>Installation Qualification Report</b> |                  |                     |
|                                                   | Report No: TE82943-13-IQR                | Iteration No: 01 | SAP No: TE0082943QX |

## 6.0 Qualification Results

6.1 Test Script IQ-01: Associated Documentation Verification was performed according to Installation Qualification Procedure 730004135, Ver. 00. The completed Test Script Data Sheet is provided as Attachment 7.3.

6.1.1 The Acquity BSM Pump Automated Final Test Procedure 735002010, Rev. L, Ver. 10 was confirmed to be in SAP with a status of Ready, as evidenced below:

| Document List After Selection 11 Hits   |           |    |                                       |                 |                | Waters |
|-----------------------------------------|-----------|----|---------------------------------------|-----------------|----------------|--------|
|                                         |           |    |                                       |                 |                |        |
| Rev/Lev Type                            | Document  | Vs | Description                           | Status text     | Long name      |        |
| A TSP                                   | 735002010 | 00 | AcQuity BSM Pump Automated Final Test | RELEASE GENERAL | Edward Jackson |        |
| B TSP                                   | 735002010 | 01 | AcQuity BSM Pump Automated Final Test | RELEASE GENERAL | Edward Jackson |        |
| C TSP                                   | 735002010 | 02 | AcQuity BSM Pump Automated Final Test | RELEASE GENERAL | Edward Jackson |        |
| D TSP                                   | 735002010 | 03 | AcQuity BSM Pump Automated Final Test | RELEASE GENERAL | Edward Jackson |        |
| E TSP                                   | 735002010 | 04 | AcQuity BSM Pump Automated Final Test | RELEASE GENERAL | Edward Jackson |        |
| F TSP                                   | 735002010 | 05 | AcQuity BSM Pump Automated Final Test | RELEASE GENERAL | Edward Jackson |        |
| G TSP                                   | 735002010 | 06 | AcQuity BSM Pump Automated Final Test | RELEASE GENERAL | Edward Jackson |        |
| H TSP                                   | 735002010 | 07 | AcQuity BSM Pump Automated Final Test | RELEASE GENERAL | Edward Jackson |        |
| J TSP                                   | 735002010 | 08 | AcQuity BSM Pump Automated Final Test | RELEASE GENERAL | Edward Jackson |        |
| K TSP                                   | 735002010 | 09 | AcQuity BSM Pump Automated Final Test | RELEASE GENERAL | Edward Jackson |        |
| <input checked="" type="checkbox"/> TSP | 735002010 | 10 | AcQuity BSM Pump Automated Final Test | READY           | Edward Jackson |        |

6.1.2 The Acquity QSM Final Instrument Test Procedure 735002155, Rev. H, Ver. 07 was confirmed to be in SAP with a status of Ready, as evidenced below:

| Document List After Selection 8 Hits    |           |    |                                   |                 |                | Waters |
|-----------------------------------------|-----------|----|-----------------------------------|-----------------|----------------|--------|
|                                         |           |    |                                   |                 |                |        |
| Rev/Lev Type                            | Document  | Vs | Description                       | Status text     | Long name      |        |
| A TSP                                   | 735002155 | 00 | Acquity QSM Final Instrument Test | RELEASE GENERAL | Edward Jackson |        |
| B TSP                                   | 735002155 | 01 | Acquity QSM Final Instrument Test | RELEASE GENERAL | Edward Jackson |        |
| C TSP                                   | 735002155 | 02 | Acquity QSM Final Instrument Test | RELEASE GENERAL | Edward Jackson |        |
| D TSP                                   | 735002155 | 03 | Acquity QSM Final Instrument Test | RELEASE GENERAL | Edward Jackson |        |
| E TSP                                   | 735002155 | 04 | Acquity QSM Final Instrument Test | RELEASE GENERAL | Edward Jackson |        |
| F TSP                                   | 735002155 | 05 | Acquity QSM Final Instrument Test | RELEASE GENERAL | Daniel Guerlin |        |
| G TSP                                   | 735002155 | 06 | Acquity QSM Final Instrument Test | RELEASE GENERAL | Edward Jackson |        |
| <input checked="" type="checkbox"/> TSP | 735002155 | 07 | Acquity QSM Final Instrument Test | READY           | Edward Jackson |        |

6.1.3 The Calibration / Maintenance for TE82943 Procedure 735001828, Rev. E, Ver. 04 was confirmed to be in SAP with a status of Release General, as evidenced below:

| Document List After Selection 5 Hits      |           |    |                                          |                 |                | Waters |
|-------------------------------------------|-----------|----|------------------------------------------|-----------------|----------------|--------|
|                                           |           |    |                                          |                 |                |        |
| Rev/Lev Type                              | Document  | Vs | Description                              | Status text     | Long name      |        |
| A CAL                                     | 735001828 | 00 | AcQuity BSM Automated Tester Calibration | RELEASE GENERAL | Edward Jackson |        |
| B CAL                                     | 735001828 | 01 | AcQuity SDS Automated Tester Calibration | RELEASE GENERAL | Edward Jackson |        |
| C CAL                                     | 735001828 | 02 | AcQuity BSM Automated Tester Calibration | RELEASE GENERAL | Edward Jackson |        |
| D CAL                                     | 735001828 | 03 | Calibration/Maintenance for TE82943      | RELEASE GENERAL | Edward Jackson |        |
| <input checked="" type="checkbox"/> E CAL | 735001828 | 04 | Calibration/Maintenance for TE82943      | RELEASE GENERAL | Edward Jackson |        |

|                                                  |                                          |                            |  |
|--------------------------------------------------|------------------------------------------|----------------------------|--|
| <b>Waters</b><br>THE SCIENCE OF WHAT'S POSSIBLE™ | <b>Installation Qualification Report</b> |                            |  |
| <b>Report No: TE82943-13-IQR</b>                 | <b>Iteration No: 01</b>                  | <b>SAP No: TE0082943QX</b> |  |

- 6.2 Test Script IQ-02: Site Verification and Test Script IQ-03: Instrumentation Calibration Verification were not performed as part of this Qualification according to TE82943-28MAR2018-VAF.
- 6.2.1 All results can be found in the previously executed TE82943-13-IQR\_iteration 00, which can be found in the TE0082943QX directory of SAP. This remains a valid qualification for the TE82943-13 system.
- 6.3 Test Script IQ-04: Software and Instrument Firmware Version was performed according to Installation Qualification Procedure 730004135, Ver. 00. The completed Test Script Data Sheet is provided as Attachment 7.4.
- 6.3.1 The BSM Test Equipment Software version listed in the Acquity BSM Pump Automated Final Test Procedure 735002010, Rev. L, Ver. 10 is Test Software 2.2 and was verified to match the version listed on the passing test record. Refer to Attachment 7.8.
- 6.3.2 The QSM Test Equipment Software version listed in the Acquity QSM Final Instrument Test Procedure 735002155, Rev. H, Ver. 07 is Test Software 1.7 and was verified to match the version listed on the passing test record. Refer to Attachment 7.5 or Attachment 7.7.
- 6.3.3 The firmware version for P/N: 186015080 listed in ECR #9221562 is version 1.71.381 and was verified to match the version listed on the test record. Refer to Attachment 7.7.
- 6.3.4 The firmware version for P/N: 186015001 listed in ECR #9221631 is version 1.71.387 and was verified to match the version listed on the test record. Refer to Attachment 7.8.
- 6.3.5 The firmware version for P/N: 186015018 listed in ECR #9221630 is version 1.71.381 and was verified to match the version listed on the test record. The passing test record is provided as Attachment 7.5.
- 6.4 Test Script IQ-05: General Safety and Alarms was not performed as part of this qualification according to TE82943-28MAR2018-VAF.
- 6.4.1 All results can be found in the previously executed TE82943-13-IQR\_iteration 00, which can be found in the TE0082943QX directory of SAP. This remains a valid qualification for the TE82943-13 system.
- 6.5 Test Script IQ-06: Functional Verification was performed according to Installation Qualification Procedure 730004135, Ver. 00. The completed Test Script Data Sheet is provided as Attachment 7.6.
- 6.5.1 One (1) Acquity UPLC H-Class QSM Plus (P/N: 186015080, S/N: D18QSP002A) was tested using the Acquity SDS Automated Test System (TE82943-13) with all tests passing. The passing test record is provided as Attachment 7.7.
- 6.5.2 One (1) Acquity UPLC BSM (P/N: 186015001, S/N: D18UPB453A) was tested using the Acquity SDS Automated Test System (TE82943-13) with all tests passing. The passing test record is provided as Attachment 7.8.
- 6.6 This table provides a summary of each test script as performed according to 730004135, Ver. 00 along with the attachment location of all objective evidence. The table also indicates any deviation taken from the scripts during qualification.

| Script or Section | Pass/Fail | Objective Evidence                | Deviations                    |
|-------------------|-----------|-----------------------------------|-------------------------------|
| IQ-01             | Pass      | Attachment 7.3                    | None                          |
| IQ-04             | Pass      | Attachment 7.4, 7.5, 7.7, and 7.8 | <del>One: see §8.2</del> None |
| IQ-06             | Pass      | Attachments 7.6, 7.7, and 7.8     | One: see §8.1                 |

- 7.0 **Attachments**
- 7.1 Completed Operator Training Record
- 7.2 Completed Executor Training Record
- 7.3 Completed Test Script IQ-01: Associated Document Verification

Template 730002845, Version 02  
 Ref. 730001835, Process Validation Procedure for Milford Site

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|                                                                  |  |                                          |                            |
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| <b>Waters</b><br><small>THE SCIENCE OF WHAT'S POSSIBLE.™</small> |  | <b>Installation Qualification Report</b> |                            |
| <b>Report No: TE82943-13-IQR</b>                                 |  | <b>Iteration No: 01</b>                  | <b>SAP No: TE0082943QX</b> |

- 7.4 Completed Test Script IQ-04: Test Software and Instrument Firmware Version
- 7.5 Objective Evidence IQ-04: Passing Test Record for UUT Part #186015018 (S/N: D18QSM152A)
- 7.6 Completed Test Script IQ-06: Functional Verification
- 7.7 Objective Evidence IQ-06: Passing Test Record for UUT Part #186015080 (S/N: D18QSP002A)
- 7.8 Objective Evidence IQ-06: Passing Test Record for UUT Part #186015001 (S/N: D18UPB453A)

#### 8.0 Deviation from Test Equipment Qualification

There were two deviations generated during the execution of the Installation Qualification Procedure 730004135, Ver. 00.

- 8.1 Description: P/N: 186015082 was not tested as part of this qualification as specified in TE82943-28MAR2018-VAF.

Proposed Corrective Action: There is no need to test P/N: 186015082 because the part is not built or tested at this site.

Resolution: No resolution necessary. Functional tests of P/N: 186015080, P/N: 186015001, and P/N: 186015018 are sufficient to prove the functionality of this test system.

- 8.2 Description: ~~The firmware Acceptance Criteria for P/N: 186015018 was listed in Test Script IQ-04: Test Software and Firmware Verification as version 1.71.387 instead of 1.71.381.~~

~~Proposed Corrective Action: The typographical error was manually corrected to version 1.71.381 and the downloaded firmware version was verified to match the version specified in ECR #9221630.~~

~~Resolution: No resolution necessary. The correct firmware version was verified as intended.~~

#### 9.0 References

The current approved versions of the following documents are referenced within this report:

| Document Number             | Document Title                                                           |
|-----------------------------|--------------------------------------------------------------------------|
| 730004135, Ver. 00          | Installation Qualification Procedure                                     |
| 735002010, Rev. L, Ver. 10  | Acquity BSM Pump Automated Test Procedure                                |
| 735002155, Rev. H, Ver. 07  | Acquity QSM Final Instrument Test Procedure                              |
| 735001828, Rev. E, Ver. 04  | Calibration / Maintenance for TE82943 Procedure                          |
| ECR #9221562                | Engineering Change Request Releasing Emerald Firmware for New Parts      |
| ECR #9221630                | Engineering Change Request Releasing Emerald Firmware for Existing Parts |
| ECR #9221631                | Engineering Change Request Releasing Emerald Firmware for Existing Parts |
| TMD010478 Ver. 01           | Temporary Manufacturing Deviation for Bifrost Validation                 |
| TE82943-28MAR2018-VAF       | Validation Assessment Form for Bifrost Part Number Add                   |
| TE82943-13-IQR_iteration 00 | Installation Qualification Report for TE82943-13                         |

Title: Individual Training Form

Document No: 730002657

Version No: 00

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|                  |                                       |                          |        |
|------------------|---------------------------------------|--------------------------|--------|
| Training Type:   | Read and Understood                   |                          |        |
| Name:            | ANG KIN CHEONG                        | Employee ID <sup>1</sup> | 246025 |
| Date of Training | 16 APR 2018                           |                          |        |
| Comments:        | N/A this section on the original copy |                          |        |

| Document Number | Title                                  | Rev. # |
|-----------------|----------------------------------------|--------|
| 735002010       | Acquity BSM Pump Automated Test        | L      |
| 735002155       | Acquity QSM Pump Final Instrument Test | H      |
|                 |                                        |        |
|                 |                                        |        |
|                 |                                        |        |
|                 |                                        |        |
|                 |                                        |        |
|                 |                                        |        |
|                 |                                        |        |
|                 |                                        |        |
|                 |                                        |        |

|                                                                                     |                   |             |
|-------------------------------------------------------------------------------------|-------------------|-------------|
|  | MASTER TECHNICIAN | 16 APR 2018 |
| Employee's Signature                                                                | Title             | Date        |
|  | SENIOR ENGINEER   | 16 APR 2018 |
| Trainer's Signature                                                                 | Title             | Date        |

Document No.: TE82943-13-IQR  
Iteration No.: 01  
Attachment: 7.1 Page: 1 of 1

<sup>1</sup> Without preceding "90"

|                         |                     |                     |        |
|-------------------------|---------------------|---------------------|--------|
| <b>Training Type:</b>   | Read and Understood |                     |        |
| <b>Name:</b>            | CHAN YEE HWA        | <b>Employee ID:</b> | 618056 |
| <b>Date of Training</b> | 07 MAR 2018         |                     |        |
| <b>Comments:</b>        | N/A                 |                     |        |

[illegible]

|                                                                                     |                        |            |
|-------------------------------------------------------------------------------------|------------------------|------------|
|  | MANUFACTURING ENGINEER | 7 MAR 2018 |
| Employee's Signature                                                                | Title                  | Date       |

|                     |       |      |
|---------------------|-------|------|
| N/A                 | N/A   | N/A  |
| Trainer's Signature | Title | Date |

Document No.: TE82943-13-IQR  
Iteration No.: 01  
Attachment: 7.2 Page: 1 of 1

<sup>1</sup> Without preceding "90"



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WORK INSTRUCTION / OPERATING PROCEDURE

Title: Installation Qualification Procedure

Document No: 730004135

Version No: 00

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| IQ Test Name: Associated Documentation Verification                                                                                                                                                                                                                                                                                                                                                                                                                                                      |                                                                         | Test Script No.: IQ-01                                                 |                |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------|------------------------------------------------------------------------|----------------|
| Equipment No./ID: TE82943-13                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |                                                                         | Equipment Name: Acquity SDS Final Test System                          |                |
| Installation Site: Flextronics: WPPL, Singapore                                                                                                                                                                                                                                                                                                                                                                                                                                                          |                                                                         |                                                                        |                |
| <b>Purpose:</b><br>To verify that supporting documentation is available prior to the completion of qualification.                                                                                                                                                                                                                                                                                                                                                                                        |                                                                         |                                                                        |                |
| <b>Test Execution:</b><br>List all applicable documents (Preventive Maintenance, Calibration, Operating Procedures, Test Specification Procedures, Manufacturing Procedures, etc.) under the Document type header and then complete the table below. If applicable documents are unavailable state why in the comments section. All applicable documents must be in either Ready, Pre-Rel-Prod, or Release General state in SAP. Enter N/A for any parameter or cell that is not used or not applicable. |                                                                         |                                                                        |                |
| <b>Objective Evidence:</b><br>Completed Test Script Data Sheet                                                                                                                                                                                                                                                                                                                                                                                                                                           |                                                                         |                                                                        |                |
| SAP Screen shot of below available document(s)                                                                                                                                                                                                                                                                                                                                                                                                                                                           |                                                                         |                                                                        |                |
| Document Type                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            | Title, Doc No., Revision/Version No                                     | Status in SAP                                                          | Initial & Date |
| TSP                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      | Acquity BSM Pump Automated Final Test TSP<br>735002010, Rev. L, Ver. 10 | READY                                                                  | YH 05 APR 2018 |
| TSP                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      | Acquity QSM Final Instrument Test TSP<br>735002155, Rev. H, Ver. 07     | READY                                                                  | YH 05 APR 2018 |
| CAL                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      | Calibration / Maintenance for TE82943<br>735001828, Rev. E, Ver. 04     | RELEASE<br>GENERAL                                                     | YH 05 APR 2018 |
| <b>Comments:</b><br><br><div style="text-align: center;">N/A <br/>05 APR 2018</div>                                                                                                                                                                                                                                                                                                                                   |                                                                         |                                                                        |                |
| <b>Overall Test Conclusion:</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |                                                                         | <input checked="" type="checkbox"/> Pass <input type="checkbox"/> Fail |                |

Copy this Test Script as needed

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Template 730000483 V06

It is the responsibility of the user to verify they are using the current released version.  
HARD COPY UNCONTROLLED UNLESS STAMPED, SIGNED AND DATED BY AUTHORISED PERSONNEL

Document No. : TE82943-13-IQR  
Iteration No : 01  
Attachment : 7.3 Page : 1 of 1

## Title: Installation Qualification Procedure

Document No: 730004135

Version No: 00

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| IQ Test Name: Test Software and Instrument Firmware Version                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |                     |                                               | Test Script No.: IQ-04 |                |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------|-----------------------------------------------|------------------------|----------------|
| Equipment No./ID: TE82943-13                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |                     | Equipment Name: Acquity SDS Final Test System |                        |                |
| Installation Site: Flextronics: WPPL, Singapore                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |                     |                                               |                        |                |
| <p><b>Purpose:</b><br/>To verify that the installed firmware/software is correct per the applicable design/operational documents (TSP, ASP, MPR, BOM, and/or other Design documents).</p> <p><b>Test Execution:</b><br/>List all critical instruments/components and/or sub-systems that require software and/or firmware in the Description column. List the associated required software/firmware version, as defined in the applicable design/operational documents, in the Acceptance criteria column. Verify that the software/firmware version on the Test Equipment match the acceptance criteria and are identical. Enter N/A for any parameter or cell that is not used or applicable.</p> <p><b>Objective Evidence:</b><br/>Completed Test Script Data Sheet<br/>Identify the applicable design/operational document that defined the required software/firmware version(s) in the associated Installation Qualification Report.</p> |                     |                                               |                        |                |
| Description                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    | Acceptance Criteria | As Found                                      | Pass/Fail              | Initial & Date |
| BSM Test Equipment Software                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    | Version: 2.2        | Version: 2.2                                  | PASS                   | YH 05 APR 2018 |
| QSM Test Equipment Software                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    | Version: 1.7        | Version: 1.7                                  | PASS                   | YH 03 APR 2018 |
| Instrument Firmware P/N: 186015080                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             | Version: 1.71.381   | Version: 1.71.381                             | PASS                   | YH 03 APR 2018 |
| Instrument Firmware P/N: 186015001                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             | Version: 1.71.387   | Version: 1.71.387                             | PASS                   | YH 03 APR 2018 |
| Instrument Firmware P/N: 186015018                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             | Version: 1.71.381   | Version: 1.71.381                             | PASS                   | YH 05 APR 2018 |
| <p><b>Comments:</b><br/>BSM software version specified in 735002010, Ver. 10<br/>QSM software version specified in 735002155, Ver. 07<br/>Firmware for P/N: 186015080 in ECR #9221562<br/>Firmware for P/N: 186015001 specified in ECR #9221631<br/>Firmware for P/N: 186015018 specified in ECR #9221630<br/><del>see deviation 5.2.2</del> not necessary because this deviation doesn't exist.<br/>Please reprint this script and fill out again without this comment.</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |                     |                                               |                        |                |
| <p><b>Overall Test Conclusion:</b> <input checked="" type="checkbox"/> Pass <input type="checkbox"/> Fail</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |                     |                                               |                        |                |

Copy this Test Script as needed

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Template 730000483 V06

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Document No. : TE82943-13-2AR  
Iteration No. : 01  
Attachment : 7.4 Page : 1 of 1

# Waters Corporation - Test Record

Part Number: 186015018  
 Operator: 246025  
 Serial Number: D18QSM152A  
 Test System: TE82943-13  
 Test Software: 1.7

Product: Acquity QSM  
 Start Time: 04/23/2018, 17:00:  
 End Time: 04/23/2018, 19:19:  
 Order: N/A  
 Location: Flextronics, SG

Firmware: 1.71.381 (Feb 14 2018 10:01:23)

| Name                                              | LSL   | Measurement | USL   | Unit    | Outcome |
|---------------------------------------------------|-------|-------------|-------|---------|---------|
| Test Electrical Safety                            |       |             |       |         | PASS    |
| Test Loader Download                              |       |             |       |         | PASS    |
| Test Reboot Firmware                              |       |             |       |         | PASS    |
| Test Firmware Version                             |       |             |       |         | PASS    |
| Test Instrument Type                              |       |             |       |         | PASS    |
| Test Serial Number                                |       |             |       |         | PASS    |
| Test Alarms at Bootup                             |       |             |       |         | PASS    |
| Test Gradient Start Input SHORT                   |       |             |       |         | PASS    |
| Test Gradient Start Input OPEN                    |       |             |       |         | PASS    |
| Test Stop Flow Input SHORT                        |       |             |       |         | PASS    |
| Test Stop Flow Input OPEN                         |       |             |       |         | PASS    |
| Test Leak Detect Connected                        |       |             |       |         | PASS    |
| Test Leak Detect Disconnected                     |       |             |       |         | PASS    |
| Test Leak Detect Leak                             |       |             |       |         | PASS    |
| Test Alarms Recheck                               |       |             |       |         | PASS    |
| Test Seal Wash Pump Prime/Flow                    | 2     | 3.4         | 5     | ml/min  | PASS    |
| Test Input D Prime with MeOH                      | 10    | 31          | 85    | PSI     | PASS    |
| Test Input C Prime with MeOH                      | 10    | 31.4        | 85    | PSI     | PASS    |
| Test Input B Prime with MeOH                      | 10    | 31.5        | 85    | PSI     | PASS    |
| Test Input A Prime with MeOH                      | 10    | 33          | 85    | PSI     | PASS    |
| Test Degasser Pressure                            | 0     | 0.71        | 1.547 | PSI     | PASS    |
| Test Dynamic Leak - Accumulator Leak Rate         | 5     | 30          | 149.9 | nL/min  | PASS    |
| Test Dynamic Leak - Accumulator Percent of Stroke | 1     | 23          | 30    | %       | PASS    |
| Test Dynamic Leak - Accumulator Compressed Volume | 1     | 13          | 50    | uL      | PASS    |
| Test Dynamic Leak - Accum. Maximum Pressure       | 14000 | 14024       | 15000 | psi     | PASS    |
| Test Dynamic Leak - Primary Leak Rate             | 5     | 19          | 149.9 | nL/min  | PASS    |
| Test Dynamic Leak - Primary Percent of Stroke     | 1     | 23          | 50    | %       | PASS    |
| Test Dynamic Leak - Primary Compressed Volume     | 1     | 13          | 50    | uL      | PASS    |
| Test Dynamic Leak - Primary Maximum Pressure      | 12000 | 12018       | 13000 | psi     | PASS    |
| Test Flow Rate Accuracy 2.0ml/min                 | 1.98  | 2.012       | 2.02  | ml/min  | PASS    |
| Test Pressure Ripple at 2 ml/min                  | 0     | 5           | 15    | PSI     | PASS    |
| Test Flow Rate Accuracy 0.5ml/min                 | 0.495 | 0.501       | 0.505 | ml/min  | PASS    |
| Test Static Leak Decay Vent Valve to Filter/Mixer | 1     | 18          | 250   | PSI/min | PASS    |
| Test High Pressure                                | 9000  | 10724       | 14000 | PSI     | PASS    |
| Test Compositional Accuracy - AC90%AU             | 89.5  | 90.08       | 90.5  | %       | PASS    |
| Test Compositional Accuracy - BD90%AU             | 89.5  | 89.82       | 90.5  | %       | PASS    |
| Test Compositional Accuracy - BD10%AU             | 9.5   | 10.2        | 10.5  | %       | PASS    |
| Test Compositional Accuracy - AC10%AU             | 9.5   | 10.26       | 10.5  | %       | PASS    |
| Test Serial Number Re-verification                |       |             |       |         | PASS    |
| Test Fans                                         |       |             |       |         | PASS    |
| Test LEDs                                         |       |             |       |         | PASS    |

**Acquity QSM Final Test Overall Result - PASS**

Signed: Syed 8478384

Date: 23 APR 2018

END OF DATA

Ser. No.: D18QSM152A

Page 1 of 1

Document No.: TE82943-13-104

Iteration No.: 01

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| IQ Test Name: Functional Verification                                                                                                                                                                                                                                                                                                                                                    |                                                               | Test Script No.: IQ-06                        |                |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------|-----------------------------------------------|----------------|
| Equipment No./ID: TE82943-13                                                                                                                                                                                                                                                                                                                                                             |                                                               | Equipment Name: Acquity SDS Final Test System |                |
| Installation Site: Flextronics: WPPL, Singapore                                                                                                                                                                                                                                                                                                                                          |                                                               |                                               |                |
| <b>Purpose:</b><br>To verify that system transfer and/or qualification activities have not adversely affected system functionality.                                                                                                                                                                                                                                                      |                                                               |                                               |                |
| <b>Test Execution:</b><br>One UUT shall be tested to verify that the test equipment functions as expected. If the system creates and/or tests more than one part number, the UUT to be tested per this Script should be a "worst case" product, and defined within the associated Installation Qualification Report. Enter N/A for any parameter or call that is not used or applicable. |                                                               |                                               |                |
| <b>Objective Evidence:</b><br>Completed Test Script Data Sheet<br>Copy of the system Test Record for the UUT, if applicable.                                                                                                                                                                                                                                                             |                                                               |                                               |                |
| UUT Part Number/Serial Number                                                                                                                                                                                                                                                                                                                                                            | Acceptance Criteria                                           | Pass/Fail                                     | Initial & Date |
| UUT Part Number: 186015080<br>UUT Serial Number: D19A3P002A                                                                                                                                                                                                                                                                                                                              | All required CTQ Specification measurements result in a Pass. | PASS                                          | YH 25 APR 2018 |
| UUT Part Number: 186015001<br>UUT Serial Number: D18UPB453A                                                                                                                                                                                                                                                                                                                              | All required CTQ Specification measurements result in a Pass. | PASS                                          | YH 25 APR 2018 |
| <b>Comments:</b><br><div style="text-align: center;">  <p>N/A 25 APR 2018</p> </div>                                                                                                                                                                                                                  |                                                               |                                               |                |
| <b>Overall Test Conclusion:</b> <input checked="" type="checkbox"/> Pass <input type="checkbox"/> Fail                                                                                                                                                                                                                                                                                   |                                                               |                                               |                |

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Template 730000483 V06

Document No.: TE82943-13-1AR

Iteration No.: 01

Attachment: T-6 Page 1 of 1

# Waters Corporation - Test Record

Part Number: 186015080  
 Operator: 246025  
 Serial Number: D18QSP002A  
 Test System: TE82943-13  
 Test Software: 1.7

Product: Acquity QSM PLUS  
 Start Time: 04/23/2018 09:13:  
 End Time: 04/23/2018 11:12:  
 Order: N/A  
 Location: Flextronics, SG

TMD: TMD010485  
 Firmware: 1.71.381 (Feb 14 2018 10:01:23)

| Name                                              | LSL   | Measurement | USL   | Unit    | Outcome |
|---------------------------------------------------|-------|-------------|-------|---------|---------|
| Test Electrical Safety                            |       |             |       |         | PASS    |
| Test Loader Download                              |       |             |       |         | PASS    |
| Test Reboot Firmware                              |       |             |       |         | PASS    |
| Test Firmware Version                             |       |             |       |         | PASS    |
| Test Instrument Type                              |       |             |       |         | PASS    |
| Test Serial Number                                |       |             |       |         | PASS    |
| Test Alarms at Bootup                             |       |             |       |         | PASS    |
| Test Gradient Start Input SHORT                   |       |             |       |         | PASS    |
| Test Gradient Start Input OPEN                    |       |             |       |         | PASS    |
| Test Stop Flow Input SHORT                        |       |             |       |         | PASS    |
| Test Stop Flow Input OPEN                         |       |             |       |         | PASS    |
| Test Leak Detect Connected                        |       |             |       |         | PASS    |
| Test Leak Detect Disconnected                     |       |             |       |         | PASS    |
| Test Leak Detect Leak                             |       |             |       |         | PASS    |
| Test Alarms Recheck                               |       |             |       |         | PASS    |
| Test Seal Wash Pump Prime/Flow                    | 2     | 2.9         | 5     | ml/min  | PASS    |
| Test Input D Prime with MeOH                      | 10    | 31.4        | 85    | PSI     | PASS    |
| Test Input C Prime with MeOH                      | 10    | 30.8        | 85    | PSI     | PASS    |
| Test Input B Prime with MeOH                      | 10    | 29.9        | 85    | PSI     | PASS    |
| Test Input A Prime with MeOH                      | 10    | 29.5        | 85    | PSI     | PASS    |
| Test Degasser Pressure                            | 0     | 0.76        | 1.547 | PSI     | PASS    |
| Test Dynamic Leak - Accumulator Leak Rate         | 5     | 46          | 149.9 | nL/min  | PASS    |
| Test Dynamic Leak - Accumulator Percent of Stroke | 1     | 24          | 30    | %       | PASS    |
| Test Dynamic Leak - Accumulator Compressed Volume | 1     | 14          | 50    | uL      | PASS    |
| Test Dynamic Leak - Accum. Maximum Pressure       | 14000 | 14020       | 15000 | psi     | PASS    |
| Test Dynamic Leak - Primary Leak Rate             | 5     | 34          | 149.9 | nL/min  | PASS    |
| Test Dynamic Leak - Primary Percent of Stroke     | 1     | 23          | 50    | %       | PASS    |
| Test Dynamic Leak - Primary Compressed Volume     | 1     | 13          | 50    | uL      | PASS    |
| Test Dynamic Leak - Primary Maximum Pressure      | 12000 | 12017       | 13000 | psi     | PASS    |
| Test Flow Rate Accuracy 2.0ml/min                 | 1.98  | 2.015       | 2.02  | ml/min  | PASS    |
| Test Pressure Ripple at 2 ml/min                  | 0     | 4           | 15    | PSI     | PASS    |
| Test Flow Rate Accuracy 0.5ml/min                 | 0.495 | 0.503       | 0.505 | ml/min  | PASS    |
| Test Static Leak Decay Vent Valve to Filter/Mixer | 1     | 20          | 250   | PSI/min | PASS    |
| Test High Pressure                                | 9000  | 10762       | 14000 | PSI     | PASS    |
| Test Compositional Accuracy - AC90%AU             | 89.5  | 89.97       | 90.5  | %       | PASS    |
| Test Compositional Accuracy - BD90%AU             | 89.5  | 89.86       | 90.5  | %       | PASS    |
| Test Compositional Accuracy - BD10%AU             | 9.5   | 10.12       | 10.5  | %       | PASS    |
| Test Compositional Accuracy - AC10%AU             | 9.5   | 10.18       | 10.5  | %       | PASS    |
| Test Serial Number Re-verification                |       |             |       |         | PASS    |
| Test Fans                                         |       |             |       |         | PASS    |
| Test LEDs                                         |       |             |       |         | PASS    |

## Acquity QSM PLUS Final Test Overall Result - PASS

Signed: Ang Kin Cheong 246025

Date: 23 APR 2018

END OF DATA

Document No.: TE82943-13-IQR

Iteration No.: 01

Ser. No.: D18QSP002A

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# Waters Corporation - Test Record

Part Number: 186015001  
 Operator: 246025  
 Serial Number: D18UPB453A  
 Test System: TE82943-13  
 Test Software: 2.2

Product: Acquity BSM  
 Start Time: 04/24/2018, 14:59:  
 End Time: 04/24/2018, 17:56:  
 Order: N/A  
 Location: Flextronics, SG

Firmware: 1.71.387 (Feb 14 2018 13:16:28)

| Name                                                        | LSL   | Measurement | USL   | Unit     | Outcome |
|-------------------------------------------------------------|-------|-------------|-------|----------|---------|
| Test Electrical Safety                                      |       |             |       |          | PASS    |
| Test Loader Download                                        |       |             |       |          | PASS    |
| Test Reboot Firmware for Pump B Download                    |       |             |       |          | PASS    |
| Test Firmware Version                                       |       |             |       |          | PASS    |
| Test Serial Number                                          |       |             |       |          | PASS    |
| Test Alarms at Bootup                                       |       |             |       |          | PASS    |
| Test Switch2 Output ON                                      |       |             |       |          | PASS    |
| Test Switch2 Output OFF                                     |       |             |       |          | PASS    |
| Test Switch3 Output ON                                      |       |             |       |          | PASS    |
| Test Switch3 Output OFF                                     |       |             |       |          | PASS    |
| Test Run Stopped Output ON                                  |       |             |       |          | PASS    |
| Test Run Stopped Output OFF                                 |       |             |       |          | PASS    |
| Test Switch1 Output ON                                      |       |             |       |          | PASS    |
| Test Switch1 Output OFF                                     |       |             |       |          | PASS    |
| Test Gradient Start Input SHORT                             |       |             |       |          | PASS    |
| Test Gradient Start Input OPEN                              |       |             |       |          | PASS    |
| Test Stop Flow Input SHORT                                  |       |             |       |          | PASS    |
| Test Stop Flow Input OPEN                                   |       |             |       |          | PASS    |
| Test Auxiliary1 Input SHORT                                 |       |             |       |          | PASS    |
| Test Auxiliary1 Input OPEN                                  |       |             |       |          | PASS    |
| Test Auxiliary2 Input SHORT                                 |       |             |       |          | PASS    |
| Test Auxiliary2 Input OPEN                                  |       |             |       |          | PASS    |
| Test Analog Output2 set to 2.0 VDC                          | 1.9   | 2           | 2.1   | VDC      | PASS    |
| Test Analog Output2 set to 0.0 VDC                          | -0.1  | 0           | 0.1   | VDC      | PASS    |
| Test Analog Output1 set to 2.0 VDC                          | 1.9   | 2           | 2.1   | VDC      | PASS    |
| Test Analog Output1 set to 0.0 VDC                          | -0.1  | 0           | 0.1   | VDC      | PASS    |
| Test Leak Detect Connected                                  |       |             |       |          | PASS    |
| Test Leak Detect Disconnected                               |       |             |       |          | PASS    |
| Test Leak Detect Input Low                                  |       |             |       |          | PASS    |
| Test Leak Detect Input High                                 |       |             |       |          | PASS    |
| Test Alarms Recheck                                         |       |             |       |          | PASS    |
| Test Seal Wash Pump Prime/Flow                              | 2     | 3.4         | 5     | ml/min   | PASS    |
| Test Pump A Input 2 Prime with IPA                          | 115   | 184         | 280   | PSI      | PASS    |
| Test Pump B Input 2 Prime with IPA                          | 115   | 168.8       | 280   | PSI      | PASS    |
| Test Pump A Input 1 Prime with MeOH                         | 15    | 50.5        | 85    | PSI      | PASS    |
| Test Pump B Input 1 Prime with MeOH                         | 15    | 45.2        | 85    | PSI      | PASS    |
| Test Degasser Pressure                                      | 0     | 0.58        | 1.3   | PSI      | PASS    |
| Test Degasser Switch Setting                                |       |             |       |          | PASS    |
| Test Static Leak Pump A - Accumulator Decay Rate            | 1     | 93.8        | 200   | psig/min | PASS    |
| Test Static Leak Pump A - Accumulator Compression Stroke    | 1     | 25          | 30    | %        | PASS    |
| Test Static Leak Pump A - Accumulator Inferred Leak Rate    | 0.01  | 0.11        | 0.8   | uL/min   | PASS    |
| Test Static Leak Pump A - Accum. Highest Pressure Achieved  | 14000 | 14029       | 15000 | psig     | PASS    |
| Test Static Leak Pump A - Primary Decay Rate                | 1     | 56.8        | 200   | psig/min | PASS    |
| Test Static Leak Pump A - Primary Compression Stroke        | 1     | 24          | 30    | %        | PASS    |
| Test Static Leak Pump A - Primary Inferred Leak Rate        | 0.01  | 0.06        | 0.8   | uL/min   | PASS    |
| Test Static Leak Pump A - Primary Highest Pressure Achieved | 12000 | 12004       | 13000 | psig     | PASS    |
| Test Static Leak Pump B - Accumulator Decay Rate            | 1     | 162         | 200   | psig/min | PASS    |

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|                                                             |       |       |       |          |      |
|-------------------------------------------------------------|-------|-------|-------|----------|------|
| Test Static Leak Pump B - Accumulator Compression Stroke    | 1     | 28    | 30    | %        | PASS |
| Test Static Leak Pump B - Accumulator Inferred Leak Rate    | 0.01  | 0.25  | 0.8   | uL/min   | PASS |
| Test Static Leak Pump B - Accum. Highest Pressure Achieved  | 14000 | 14016 | 15000 | psig     | PASS |
| Test Static Leak Pump B - Primary Decay Rate                | 1     | 86.8  | 200   | psig/min | PASS |
| Test Static Leak Pump B - Primary Compression Stroke        | 1     | 25    | 30    | %        | PASS |
| Test Static Leak Pump B - Primary Inferred Leak Rate        | 0.01  | 0.08  | 0.8   | uL/min   | PASS |
| Test Static Leak Pump B - Primary Highest Pressure Achieved | 12000 | 12015 | 13000 | psig     | PASS |
| Test Flow Rate Accuracy Pump A 2ml/min                      | 1.98  | 2.016 | 2.02  | ml/min   | PASS |
| Test Pump A Pressure Ripple                                 | 0     | 4     | 15    | PSI      | PASS |
| Test Flow Rate Accuracy Pump A 0.5ml/min                    | 0.495 | 0.503 | 0.505 | ml/min   | PASS |
| Test Flow Rate Accuracy Pump B 2ml/min                      | 1.98  | 2.01  | 2.02  | ml/min   | PASS |
| Test Pump B Pressure Ripple                                 | 0     | 3     | 15    | PSI      | PASS |
| Test Flow Rate Accuracy Pump B 0.5ml/min                    | 0.495 | 0.502 | 0.505 | ml/min   | PASS |
| Test Flow Rate Accuracy Pump A&B 1.0ml+1.0ml/min            | 1.98  | 1.994 | 2.02  | ml/min   | PASS |
| Test High Pressure Flow Pump A&B                            | 9000  | 10662 | 14500 | PSI      | PASS |
| Test Dynamic Leak Manifold to Filter Tube                   | 0     | 0.1   | 1     | uL/min   | PASS |
| Test Serial Number Re-verification                          |       |       |       |          | PASS |
| Test Fans                                                   |       |       |       |          | PASS |
| Test LEDs                                                   |       |       |       |          | PASS |

**Acquity BSM Final Test Overall Result - PASS**

|                                             |                          |
|---------------------------------------------|--------------------------|
| <b>Signed:</b> <i>Ang Kin Cheong 246025</i> | <b>Date:</b> 25 Apr 2018 |
|---------------------------------------------|--------------------------|

END OF DATA

Document No.: TE82943-13-IQR

Iteration No.: 01

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