

## INSTALLATION QUALIFICATION REPORT

### For the ACQUITY SDS Automated Test System (TE82943-14)

#### PREPARED BY

| Name        | Role                 | Signature | Date |
|-------------|----------------------|-----------|------|
| Luo Huazhen | Senior Test Engineer |           |      |

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

#### REVIEWED BY

| Name        | Role                        | Signature | Date |
|-------------|-----------------------------|-----------|------|
| Ernest Chua | Process Validation Engineer |           |      |

The "Reviewed By" signatures denotes agreement with the description of the qualification activities.

#### APPROVED BY

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

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

#### REVISION HISTORY

| VERSION:                                                                                                             | 05 | ORIGINATOR: | Luo Huazhen | Change ID: | N/A |
|----------------------------------------------------------------------------------------------------------------------|----|-------------|-------------|------------|-----|
| <b>SUMMARY OF CHANGE:</b> Addition of new BioBSM part number 186015061 and update of system software to version 2.4. |    |             |             |            |     |

## 1.0 PURPOSE

The purpose of this Installation Qualification Report is to detail the activities associated with the execution of 730004135, Installation Qualification Protocol, for the TE82943-14, ACQUITY SDS Automated Test System.

## 1.1 SYSTEM BACKGROUND

The TE82943-14, ACQUITY SDS Automated Test System, facilitates the final functional test of ARC QSM, BSM, ISM, M Class, QSM, and UPC2 solvent managers. Each family of products is tested on a unique test program according to the corresponding Test and Specification Procedure, as shown in the Table below:

| TE82943-ACQUITY SDS FINAL TEST SYSTEM - PROGRAMS |                                  |
|--------------------------------------------------|----------------------------------|
| PRODUCT/PROGRAM                                  | TEST AND SPECIFICATION PROCEDURE |
| ARC QSM                                          | 735003612                        |
| BSM                                              | 735002010                        |
| ISM                                              | 735002977                        |
| M-Class                                          | 735003807                        |
| QSM                                              | 735002155                        |
| UPC2                                             | 735002690                        |

Thus, the associated part number is 186015061. The system performs testing to ensure the product meets the critical to quality specifications in accordance with TSP Test Specification and Procedure 735002010, Rev P, Version 13 for the TE82943-14, ACQUITY SDS Automated Test System.

In the final test, the UUT is connected to the system and the electrical, mechanical and fluidic performance of the unit are tested. Upon completion of all testing, a Final Test Record is to be kept and maintained locally or on SigmaSure Database.

The ACQUITY SDS Automated Test System TE82943-14 is located at Flex, Singapore.

## 2.0 SCOPE

This Installation Qualification Report details the Qualification activities undertaken for the TE82943-14, ACQUITY SDS Automated Test System, based on the requirements of the executed protocol, 730004135 Ver. 03, Installation Qualification Protocol, as detailed in TE82943-VP, Iteration 01.

## 3.0 SUMMARY OF RESULTS – STATEMENT OF FITNESS FOR INTENDED USE

The TE82943-14, ACQUITY SDS Automated Test System was tested in accordance with the Installation Qualification Protocol, 730004135 Ver. 03. All Test Scripts were performed, and all objective evidence requirements have been met.

Waters now has the necessary documentation in place to ensure that the TE82943-14, 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 TE82943-14, ACQUITY SDS Automated Test System can be considered fully qualified and fit for intended use.

## 4.0 ABBREVIATIONS

The following definitions are used in this document:

| Term   | Explanation                                  |
|--------|----------------------------------------------|
| ARC    | Acquity Reduced Cost                         |
| BioBSM | An inert Binary Solvent Manager Pump         |
| BSM    | Binary Solvent Manager                       |
| cGMP   | Current Good Manufacturing Practice          |
| CTQ    | Critical to Quality                          |
| IQR    | Installation Qualification Report            |
| ISM    | Isocratic Solvent Manager                    |
| N/A    | Not Applicable                               |
| NPI    | New Product Introduction                     |
| P/N    | Part Number                                  |
| QSM    | Quaternary Solvent Manager                   |
| SAP    | Enterprise Resource Planning Software        |
| SDS    | Solvent Delivery System                      |
| TSP    | Test Specification and Procedure             |
| UPC2   | Ultra-Performance Convergence Chromatography |
| UUT    | Unit Under Test                              |
| VP     | Validation Plan                              |

## 5.0 TRAINING

The executor of this qualification was trained to the Installation Qualification Protocol, 730004135 Ver. 03. The training records are provided as Attachments 7.1. The operator of the TE82943-14, ACQUITY SDS Automated Test System was trained according to the Test Specification and Procedures 735002010, Rev P, Version 13. The training records are provided as Attachment 7.2.

## 6.0 QUALIFICATION RESULTS

6.1 Test Script IQ-01: Associated Documentation Verification was performed according to Installation Qualification Protocol 730004135, Ver. 03. The completed Test Script Data Sheet is provided as Attachment 7.3.

6.1.1 The Test Specification and Procedure 735002010, Revision P, Version 13 was confirmed to be in SAP with a status of Release General. A screen capture is provided below:

| RevLev | Type | Document  | Vs | Part | Description                           | Status text     | Current Ver | Valid From | Valid To   | Change No. | Long name      |
|--------|------|-----------|----|------|---------------------------------------|-----------------|-------------|------------|------------|------------|----------------|
| A      | TSP  | 735002010 | 00 | 000  | AcQuity BSM Pump Automated Final Test | RELEASE GENERAL |             | 18.01.2010 | 01.05.2011 | 9147753    | Edward Jackson |
| B      | TSP  | 735002010 | 01 | 000  | AcQuity BSM Pump Automated Final Test | RELEASE GENERAL |             | 02.05.2011 | 14.08.2011 | 9161161    | Edward Jackson |
| C      | TSP  | 735002010 | 02 | 000  | AcQuity BSM Pump Automated Final Test | RELEASE GENERAL |             | 15.08.2011 | 19.10.2011 | 9163994    | Edward Jackson |
| D      | TSP  | 735002010 | 03 | 000  | AcQuity BSM Pump Automated Final Test | RELEASE GENERAL |             | 20.10.2011 | 30.10.2012 | 9165480    | Edward Jackson |
| E      | TSP  | 735002010 | 04 | 000  | AcQuity BSM Pump Automated Final Test | RELEASE GENERAL |             | 31.10.2012 | 28.08.2013 | 9173931    | Edward Jackson |
| F      | TSP  | 735002010 | 05 | 000  | AcQuity BSM Pump Automated Final Test | RELEASE GENERAL |             | 29.08.2013 | 16.02.2017 | 9182095    | Edward Jackson |
| G      | TSP  | 735002010 | 06 | 000  | AcQuity BSM Pump Automated Final Test | RELEASE GENERAL |             | 17.02.2017 | 30.03.2017 | 9213525    | Edward Jackson |
| H      | TSP  | 735002010 | 07 | 000  | AcQuity BSM Pump Automated Final Test | RELEASE GENERAL |             | 31.03.2017 | 27.04.2017 | 9214810    | Edward Jackson |
| J      | TSP  | 735002010 | 08 | 000  | AcQuity BSM Pump Automated Final Test | RELEASE GENERAL |             | 28.04.2017 | 03.01.2018 | 9215465    | Edward Jackson |
| K      | TSP  | 735002010 | 09 | 000  | AcQuity BSM Pump Automated Final Test | RELEASE GENERAL |             | 04.01.2018 | 04.07.2018 | 9219025    | Edward Jackson |
| L      | TSP  | 735002010 | 10 | 000  | AcQuity BSM Pump Automated Final Test | RELEASE GENERAL |             | 05.07.2018 | 15.04.2019 | 9221398    | Edward Jackson |
| M      | TSP  | 735002010 | 11 | 000  | AcQuity BSM Pump Automated Final Test | RELEASE GENERAL |             | 16.04.2019 | 08.09.2019 | 9228666    | Edward Jackson |
| N      | TSP  | 735002010 | 12 | 000  | AcQuity BSM Pump Automated Final Test | RELEASE GENERAL |             | 09.09.2019 | 08.09.2020 | 9229308    | Edward Jackson |
| P      | TSP  | 735002010 | 13 | 000  | AcQuity BSM Pump Automated Final Test | RELEASE GENERAL |             | 09.09.2020 | 31.12.9999 | 9234533    | Edward Jackson |
|        | TSP  | 735002010 | 14 | 000  | AcQuity BSM Pump Automated Final Test | READY           |             |            |            |            | Edward Jackson |

6.1.2 The 735001828 Rev E, Version 04, the Calibration/Maintenance for TE82943 was confirmed to be in SAP with a status of Release General. A screen capture from SAP is provided as follows:

| Rev | Type | Document  | Vs | Part | Description                              | Status text     | Current Ver | Valid From | Valid To   | Change No. | Long name      |
|-----|------|-----------|----|------|------------------------------------------|-----------------|-------------|------------|------------|------------|----------------|
| A   | CAL  | 735001828 | 00 | 000  | AcQuity BSM Automated Tester Calibration | RELEASE GENERAL |             | 09.09.2008 | 07.07.2010 | 9137807    | Edward Jackson |
| B   | CAL  | 735001828 | 01 | 000  | AcQuity SDS Automated Tester Calibration | RELEASE GENERAL |             | 08.07.2010 | 16.07.2012 | 9153643    | Edward Jackson |
| C   | CAL  | 735001828 | 02 | 000  | AcQuity BSM Automated Tester Calibration | RELEASE GENERAL |             | 17.07.2012 | 25.08.2013 | 9172278    | Edward Jackson |
| D   | CAL  | 735001828 | 03 | 000  | Calibration/Maintenance for TE82943      | RELEASE GENERAL |             | 26.08.2013 | 31.01.2016 | 9182185    | Edward Jackson |
| E   | CAL  | 735001828 | 04 | 000  | Calibration/Maintenance for TE82943      | RELEASE GENERAL |             | 01.02.2016 | 31.12.9999 | 9204087    | Edward Jackson |

6.2 Test Script IQ-04: Software and Instrument Firmware Version was performed according to Installation Qualification Protocol 730004135, Ver. 03. The completed Test Script Data Sheet is provided as Attachment 7.4.

6.2.1 The Test Equipment Software version listed in 735002010, Rev P, Version 13 is Test Software 2.4. The test record of passing result is provided as Attachment 7.6.

6.2.2 The instrument firmware listed for P/N 186015061 is Version 1.72.415. A screen capture from the SAP is as follows:

| Item | Ict | Component | Component description                    | Quantity | Un | Asm                                 | SIs                      | Valid |
|------|-----|-----------|------------------------------------------|----------|----|-------------------------------------|--------------------------|-------|
| 0010 | L   | 200000188 | START UP KIT, BINARY SOLVENT MANAGER     | 1        | EA | <input checked="" type="checkbox"/> | <input type="checkbox"/> | 20.   |
| 0020 | L   | 279004320 | ASSY, bioBSM, 15K                        | 1        | EA | <input checked="" type="checkbox"/> | <input type="checkbox"/> | 20.   |
| 0030 | L   | 290000380 | ENVELOPE, OWNER DOC. W/WINDOW            | 1        | EA | <input type="checkbox"/>            | <input type="checkbox"/> | 20.   |
| 0040 | L   | 290000872 | BAG, POLY, GUSSETED, 2 MIL, 30 X 18 X 48 | 1        | EA | <input type="checkbox"/>            | <input type="checkbox"/> | 20.   |
| 0050 | L   | 290000457 | BOX, SHIPPING, ACQUITY UPLC BSM          | 1        | EA | <input type="checkbox"/>            | <input type="checkbox"/> | 20.   |
| 0060 | L   | 361000825 | ACQUITY BSM Firmware 1.72.415            | 1        | EA | <input type="checkbox"/>            | <input type="checkbox"/> | 20.   |
| 0070 | L   | WAT006277 | LABEL, CONGRATULATIONS                   | 1        | EA | <input type="checkbox"/>            | <input type="checkbox"/> | 20.   |
| 0080 | L   | WAT024406 | LABEL, INSTRUMENT SN AND PACKAGING       | 1        | EA | <input type="checkbox"/>            | <input type="checkbox"/> | 20.   |
| 0090 | L   | WAT024951 | CERTIFICATE OF FUNCTIONAL PERF           | 1        | EA | <input checked="" type="checkbox"/> | <input type="checkbox"/> | 20.   |
| 0100 | L   | WAT027033 | CABLE TIE MINIATURE                      | 1        | EA | <input type="checkbox"/>            | <input type="checkbox"/> | 20.   |
| 0110 | L   | WAT089526 | DESICCANT, ACTIVATED, BAGGED, 8 UNITS    | 2        | EA | <input type="checkbox"/>            | <input type="checkbox"/> | 20.   |

6.3 Test Script IQ-06: Functional Verification was performed according to Installation Qualification Protocol 730004135, Ver. 03. The completed Test Script Data Sheet is provided as Attachment 7.5.

6.3.1 One (1) UUT (P/N: 186015061) was tested using the TE82943-14, ACQUITY SDS Automated Test System with all tests passing, meeting the acceptance criteria of all required CTQ Specification measurements/conditions. The screenshot of passing result is provided as Attachment 7.6.

6.4 This table provides a summary of each test script as performed according to 730004135, Ver. 03 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      | Attachments 7.4, 7.5 and 7.6 | None       |
| IQ-06             | Pass      | Attachments 7.5 and 7.6      | None       |

## 7.0 ATTACHMENTS

- 7.1 Completed Executor Training Record 730004135, Ver. 03
- 7.2 Completed Operator Training Record 735002010, Rev P, Version 13
- 7.3 Completed Test Script IQ-01: Associated Document Verification
- 7.4 Completed Test Script IQ-04: Test Software and Instrument Firmware Version
- 7.5 Completed Test Script IQ-06: Functional Verification
- 7.6 Objective Evidence IQ-04 and IQ-06: Test record of passing UUT (P/N: 186015061)

## 8.0 DEVIATION FROM THE QUALIFICATION PROTOCOL

There were no deviations generated during the execution of the 730004135, Installation Qualification Procedure, Version 03, for TE82943-11, Acquity SDS Automated Test System.

## 9.0 REFERENCES

The following documents are referenced within this Report:

| Document Number              | Document title                                                          |
|------------------------------|-------------------------------------------------------------------------|
| 730004135, Ver. 03           | Installation Qualification Protocol                                     |
| 735002010, Rev P, Version 13 | Test Specification and Procedure, Acquity BSM Pump Automated Final Test |
| 735001828 Rev E, Version 04  | Calibration/Maintenance for TE82943                                     |
| TE82943-VP                   | Validation Plan for the ACQUITY SDS Final Test Program – BSM Program    |