

INSTALLATION QUALIFICATION REPORT

For the ACQUITY SDS Automated Test System (TE82943-15)

PREPARED BY

Name	Role	Signature	Date
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The "Prepared By" signature denotes that this document accurately describes the qualification activities.

REVIEWED BY

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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
SUMMARY OF CHANGE: 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 TE82943-15, ACQUITY SDS Automated Test System.

1.1 SYSTEM BACKGROUND

The TE82943-15, 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 TE82943-15, 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 TE82943-15 is located at Flex, Singapore.

2.0 SCOPE

This Installation Qualification Report details the Qualification activities undertaken for the TE82943-15, 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 TE82943-15, 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 TE82943-15, 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 TE82943-15, 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 TE82943-15, 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:

Rev/Lev	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	☒	☐	20.
0020	L	279004320	ASSY, bioBSM, 15K	1	EA	☒	☐	20.
0030	L	290000380	ENVELOPE, OWNER DOC. W/WINDOW	1	EA	☐	☐	20.
0040	L	290000872	BAG, POLY, GUSSETED, 2 MIL, 30 X 18 X 48	1	EA	☐	☐	20.
0050	L	290000457	BOX, SHIPPING, ACQUITY UPLC BSM	1	EA	☐	☐	20.
0060	L	361000825	ACQUITY BSM Firmware 1.72.415	1	EA	☐	☐	20.
0070	L	WAT006277	LABEL, CONGRATULATIONS	1	EA	☐	☐	20.
0080	L	WAT024406	LABEL, INSTRUMENT SN AND PACKAGING	1	EA	☐	☐	20.
0090	L	WAT024951	CERTIFICATE OF FUNCTIONAL PERF	1	EA	☒	☐	20.
0100	L	WAT027033	CABLE TIE MINIATURE	1	EA	☐	☐	20.
0110	L	WAT089526	DESICCANT, ACTIVATED, BAGGED, 8 UNITS	2	EA	☐	☐	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 TE82943-15, 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