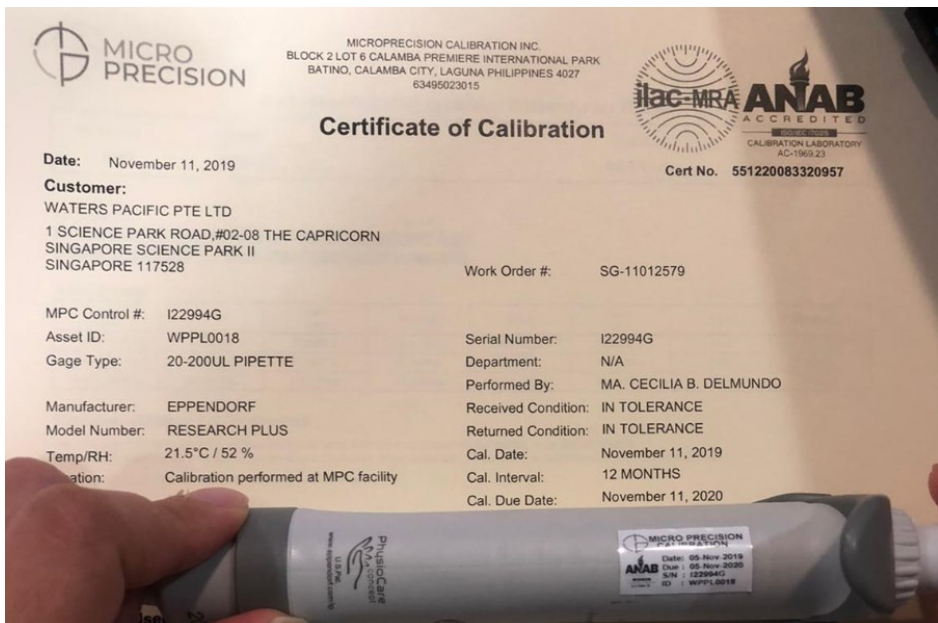


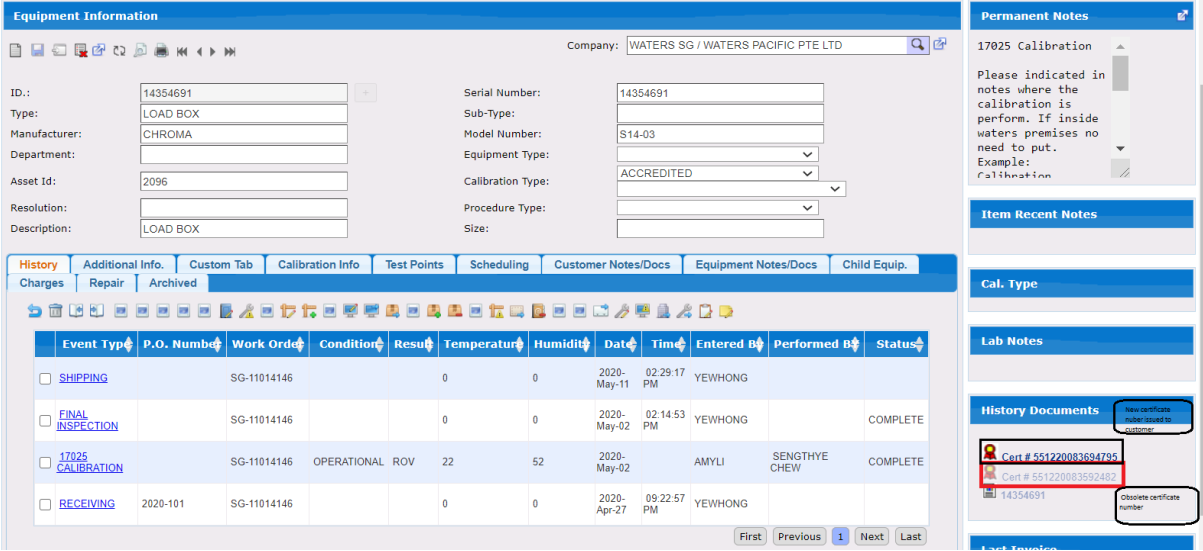
Title: **Supplier Corrective Action Request (SCAR)**

Document No: 730006714

Version No: 01

Page 1 of 9

SCAR Number SGYYMMNN	SCAR-SG200701	SCAR Assignee, Company (Supplier designated point of contact)	Amy Li Yan Yan, Micro Precision Calibration Pte Ltd
SECTION 1: INTRODUCTION (To be completed by Waters Supplier Quality / Quality Engineer)			
Source (select all that apply):			
☐	CIT Number(s): _____	☐	RMA Number(s): _____
☐	Stop Ship Number(s): _____	☐	Contract Manufacturer / Supplier declared: _____
☐	NCR Number(s): _____	☒	Other: Calibration cert no: 551220083592482 & 551220083320957
NC Statement, Requirement (Include, where applicable, part numbers, part descriptions, serial numbers, and date codes; requirement not met e.g. SOP number and revision)		Nonconformity Statement: There are multiple inaccuracies observed in the calibration records provided by Micro Precision Calibration.	
		Evidence 1: It was observed the calibration cert no. 551220083592482 dated 02 May 2020 contains multiples inaccuracies in the Notes section.	
		Evidence 2: It was observed on calibration cert no. 551220083320957 dated 11 Nov 2019 for equipment ID# WPPL0018 S/N# I22994G, the calibration date is 11 Nov 2019 and calibration due date is 11 Nov 2020. However, on the physical calibration sticker pasted on equipment by the service provider, the calibration date is 05 Nov 2019 and calibration due date is 05 Nov 2020.	
			
INITIATED BY (Waters Supplier Quality / Quality Engineer)	Name/ Title	Sign	Date
	Lim Shaynee / Supplier Quality Engineer		
APPROVAL BY (Waters Quality Manager/ Designee)	Tan Kah Chin / Senior Quality Assurance Manager		
Issuance Date	Due Date for Sections 2 and 3 (Should be within 90 days from issuance.)	Remarks (if any): N/A	
14.Jul.2020	12.Oct.2020		

SECTION 2: ROOT CAUSE ANALYSIS AND INTERIM CONTAINMENT ACTIONS	
SECTION 2A: FORM A TEAM <i>List Team Members' Names/ Function (minimum 2 personnel)</i>	Amy Li-Sales Engineer Leslie Rojas-Corporate QA
SECTION 2B: IMPLEMENTED INTERIM CONTAINMENT ACTIONS <i>(Temporary fixes to protect customer, including Correction Actions. Where applicable, Part Number(s), Part Description(s), Quantities, Action Owner should be included. If containment is documented via Waters NCR, Waters NCR number should be included).</i>	
Micro Precision had issue revised Calibration Certificate number 551220083694795, both softcopy and hard copy sent to CM_Flex. Responsible: Li Yan Yan The total of calibration certificate that MP-Singapore issued to Water SG are 177. When we review all the calibration certificate the we issued it is not affected by this issue. I will attach the list of equipment that MP-Singapore issued calibration certificate. This is the evidence that the previous cert is already obsolete.  13.07.20	
Completion Date (DD.MM.YY)	

Micro Precision will issue correct calibration sticker for equipment ID# WPPL0018 S/N# I22994G with Cal Date 11-Nov-2019 and Due Date 11-Nov-2020

Responsible: Li Yan Yan

Conduct refresher training for all quality personnel regarding on the Quality Checking, Calibration Reports Processing and Final Inspection process of the calibrated equipment. Strictly implement initial checking on all calibrated equipment to ensure if the equipment bears correct and updated calibration labels.

Responsible: Joel De Vera/ Laboratory Manager

Completion Date: July 15, 2020

Evidence

17.07.20

 **MP TRAINING RECORD**

Training Date: July 15, 2020 Page(s) 1

TRAINING TITLE:	OBJECTIVE(S):
Quality Checking and Calibration Reports Processing	- This training aims to identify guidelines on processing quality checking and calibration report. - This training covers quality checking, proper labelling of equipment up to final inspection process. Completion of calibration events and PI event on the Calibration Management Software through secured sign offs.

Attending
The following personnel attended this training session.

Name	Signature	Name	Signature
Ng Kian Hong			
Zhu Yong			
Yew Yee Hong			
Chen Ding Ting			
Chan Yock Tee			
Wai Yook Fook			
Lim Shi Yuan			
Director			

Signature: _____ Date: _____
Instructor Name: _____ Division: _____

COA-FM-002 REV. 05
(27-Apr-2018)

SECTION 2C: ROOT CAUSE ANALYSIS (RCA) AND RISK ASSESSMENT

(Objective evidence should be attached and referenced with running number e.g. Refer to Attachment 1).

Case 1:

The calibration technician unintentionally committed typographical error inputting the superseded certificate number same as the new one because he just copied the certificate number and paste it on the note. It is done by the same technician because the CSR personnel ask him to copy the superseded certificate number on the note part but he just copy the new certificate number instead of the old certificate number. And also for the Calibration Performed the technician input "at" but it should be "for" because it is calibrated in MPC Facility, See attachment 1:



Certificate of Calibration



Cert No: 551220083592482

Date: May 02, 2020

Customer:
WATERS PACIFIC PTE LTD
1 SCIENCE PARK ROAD, #02-08 THE CAPRICORN
SINGAPORE SCIENCE PARK II
SINGAPORE 117526

Work Order #: SG-11014146

MPC Control #: 14354691 **Serial Number:** 14354691

Asset ID: 2096 **Department:** N/A

Gage Type: LOAD BOX **Performed By:** SENGTHYE CHEW

Manufacturer: CHROMA **Received Condition:** OPERATIONAL

Model Number: S14-03 **Returned Condition:** REPORT OF VALUE

Size: N/A **Cal. Date:** May 02, 2020

Temp/RH: 22°C / 52 % **Cal. Interval:** 12 MONTHS

Location: Calibration performed at MPC facility **Cal. Due Date:** May 02, 2021

Calibration Notes:
The user shall determine the suitability of the equipment for its intended use.
The calibration status is defined as Report of Value.
Calibration performed at Facilities Pte Ltd.
See attached data, (1 page).
This supersedes Certificate Number 551220083592482.

REVIEWED & ACCEPTED

SIGN: [Signature]

DATE: 13 May 2020

REMARKS: End of 2019

Standards Used to Calibrate Equipment

I.D.	Description	Model	Serial	Manufacturer	Cal. Due Date	Traceability #
CA0094	MULTIMETER	3456A	2823A25598	HEWLETT PACKARD	Jun 10, 2021	1-12015829011-1

Procedures Used in this Event

Procedure Name	Description
CHROMA 190XX PRODUCT	Using a Load Box to Verify Hipot Tester, Chroma 190XX Product, Jun 15, 2019

This is the evidence that the calibration is done in MPC facility.

Work Order : SG-11014146 **Open Date :** Apr 27, 2020

Purchase Order : 2020-102 **Expected Due Date :** May 6, 2020

Status : INVOICED **Completed Date :** 5/29/20

Terms : NET 30

Gage ID	Status	Manufacturer	Model No.	Serial No.	Location	Event Type
	Asset ID	Gage Type	Cal Cycle	Completed	Performed By	
14354691	C 2096	CHROMA LOAD BOX	S14-03 12 MONTHS	14354691 7/13/20	17025 CALIBRATIO SENGTHYE CHEW	
7322788	C 2097	CHROMA LOAD BOX	S14-03 12 MONTHS	7322788 7/13/20	17025 CALIBRATIO SENGTHYE CHEW	

Total items: 2

Work Order Specific Notes:

Name	Notes	Date Inserted
JIANYINGWANG	WO#SG-11014064#14146, Invoice#SG-11014146.	May 28, 2020

Case 2:

The calibration technician unintentionally committed typographical error inputting calibration date and due date for the unit with Equipment ID# WPPL0018 S/N I22994G. The one that they input on the physical sticker is 5 Nov 2019 to 5 Nov 2020 instead of 11 Nov 2019 to 11 Nov 2020. Likewise, this information has been overlooked by Final Inspection Personnel during the Final Inspection Process if the calibration dates and calibration due dates in certificate are matched with the calibration date and due date on the physical sticker.

See Attachment 1:

Certificate of Calibration

Date: November 11, 2019
Customer: WATERS PACIFIC PTE LTD
 1 SCIENCE PARK ROAD, #02-08 THE CAPRICORN
 SINGAPORE SCIENCE PARK II
 SINGAPORE 117528

Work Order #: SG-11012579
Cert No. 551220083320957

MPC Control #: I22994G
Asset ID: WPPL0018
Gage Type: 20-200UL PIPETTE

Manufacturer: EPPENDORF
Model Number: RESEARCH PLUS
Temp/RH: 21.5°C / 52 %

Serial Number: I22994G
Department: N/A
Performed By: MA. CECILIA B. DELMUNDO
Received Condition: IN TOLERANCE
Returned Condition: IN TOLERANCE
Cal. Date: November 11, 2019
Cal. Interval: 12 MONTHS
Cal. Due Date: November 11, 2020

Location: Calibration performed at MPC facility

SECTION 2D: PLAN OF PERMANENT CORRECTIVE ACTION(S) *(Each root cause in section 2 shall be addressed. Documentation shall be uploaded s appropriate. Where applicable, Part Number(s), Part Description(s), Quantities, Action Owner should be included).*

Plan Date
(DD.MM.YY)

Conduct refresher training for all technicians regarding on the Calibration Process Flow with focused on affixing correct and updated calibration sticker on the equipment prior endorsement to QC/FI process. Implement counter checking of the Team Leader on the calibration labeling of the equipment.

Responsible: Joel De Vera/ Laboratory Manager

Completion Date: July 15, 2020

Evidence:

15.07.20

MP TRAINING RECORD

Training Date: July 15, 2020 Page(s) 1

TRAINING TITLE:
Refresher Training for Calibration Process Flow

OBJECTIVE(S):
• This training aims to refresh the team member on the Process of calibration with focused on affixing correct calibration sticker on customer equipment. And also for the customer request notes.

Attending
The following personnel attended this training session.

Name	Signature	Signature
Ng Han Beng		
Zhu Yanning		
Yoon Yee Hoon		
Chen Song Boon		
Chen Yuet Fee		
Lim Yee Hui		
Lim Yee Hui		

Instructor Name: Joel De Vera
 Position: Laboratory Manager

Date: July 15, 2020
 Division: ME-Singapore

COA-FM-002 REV. 08 (14 AUG 2018)

Conduct refresher training for all quality personnel regarding on the Quality Checking, Calibration Reports Processing and Final Inspection process of the calibrated equipment. Strictly implement initial checking on all calibrated equipment to ensure if the equipment bears correct and updated calibration labels.

Responsible: Joel De Vera/ Laboratory Manager
Completion Date: July 15, 2020

Evidence:



MICRO PRECISION
MP TRAINING RECORD

Training Date: July 15, 2020 Page(s) 1

TRAINING TITLE:	OBJECTIVE(S):
Quality Checking and Calibration Reports Processing	- This training aims to identify guidelines on processing quality checking and calibration report. - This training covers quality checking, proper labelling of equipment up to final inspection process, Completion of calibration events and FI event on the Calibration Management Software through secured sign off.

Attending
The following personnel attended this training session.

Name	Signature	Name	Signature
Ng Kai Hong	[Signature]		
Zhu Yong	[Signature]		
Yew Yee Heng	[Signature]		
Chen Seng Tay	[Signature]		
Chua Yik Tee	[Signature]		
Wai Yung Fong	[Signature]		
Lim Eui Yuen	[Signature]		
Chia Heng	[Signature]		

Signature: _____ Date: _____
Instructor Name: _____ Division: _____

COA-FM-002 REV. 06 (17-Apr-2016)

Waters has agree to split the account as per MP proposal below, The address will be the key indicator on the calibration certificate to differentiate sites of the the company, see attachment;



MICRO PRECISION CALIBRATION PTE LTD
BLOCK 5008 ANG MO KIO AVENUE 5 #07-02/03
TECHPLACE II SINGAPORE 569874
65 67484384

Certificate of Calibration

Date: August 21, 2020

Customer:

WATERS PACIFIC PTE LTD

C/O: GES SINGAPORE PTE LTD
28 MARSILING LANE
SINGAPORE 739152

Work Order #: N/A

As a part of Final Inspection we put the serial number, cal date and the company name on the outside part of the packing of the unit. And also we hire a FI personnel that will check all the unit before it is shipped out to customer. Because before the Final Inspection is done by all the CSR so we hire one personnel that task to inspect all the equipment after QC completed the certificate.

The screenshot displays the Waters SCAR system interface. The main window is titled 'FINAL INSPECTION (14384691 - WATERS SG)'. It shows a sidebar with navigation options like 'History', 'Charges', 'Repair', and 'Event Type'. The 'Event Type' section is expanded, showing a list of events including 'SHIPPING', 'FINAL INSPECTION' (which is circled in blue), '17025 CALIBRATION', and 'RECEIVING'. The main area displays equipment information for 'WATERS SG / WATERS PACIFIC PTE LTD', including fields for Date (2020-May-02), P.O. Number, and Work Order (SG-11014146). A comments section contains text: 'Checked With Slicker', 'Checked with CAL DATE & CAL DUE DATE', and 'Checked With Void'. On the right, there are sections for 'Permanent Notes', 'Item Recent Notes', 'Cal. Type', 'Lab Notes', 'History Documents', and 'Last Invoice'.

SECTION 2E: PLAN ACTION(S) TO PREVENT RECURRENCE *(Shall prevent problems on similar products, processes, locations or families. Documentation shall be updated as appropriate. Where applicable, Part Number(s), Part Description(s), Quantities, Action Owner should be included).*

Plan Date
(DD.MM.YY)

Root Cause Category

Select from Dropdown

Remarks (if any):

SUBMISSION BY *(by SCAR Assignee)*

Req?

Name/ Title

Sign

Date

X

RCA APPROVAL

**Quality Manager/
Quality Supervisor**
(of SCAR Assignee)

X

**Waters Supplier
Quality / Quality
Engineer**

X

Other

☐

Remarks (if any):

Title: **Supplier Corrective Action Request (SCAR)**

Document No: 730006714

Version No: 01

Page 8 of 9

SECTION 3A: IMPLEMENTATION OF PERMANENT CORRECTIVE ACTION(S) <i>(Attach evidence)</i>			Completion Date <i>(DD.MM.YY)</i>
SECTION 3B: ACTION(S) TO PREVENT RECURRENCE <i>(Attach evidence)</i>			Completion Date <i>(DD.MM.YY)</i>
SUBMISSION BY <i>(by SCAR Assignee)</i>	Name/ Title	Sign	Date

SECTION 4: VERIFICATION AND VALIDATION <i>(Shall confirm that actions do not adversely affect the finished device. Examples: Refer to: ECO Number, Validation Protocol Number, Risk Management File. Where not applicable, document rationale).</i>			Completion Date <i>(DD.MM.YY)</i>	
Verification of Effectiveness: <i>(Evidence reviewed to confirm effectiveness of actions; such as number of records monitored).</i>	Acceptance Criteria: <i>(Results that needs to be observed for actions to be deemed effective).</i>		Result <i>(Pass/ Fail)</i>	
			<i>Choose an item</i>	
Remarks (if any): ☐ Attached extension request WPPL-FM-25.				
SUBMISSION BY <i>(by SCAR Assignee)</i>	Req?	Name/ Title	Sign	Date
	X			

APPROVAL	Quality Manager/ Quality Supervisor <i>(of SCAR Assignee)</i>	X			
	Management Rep/ QMS In-Charge <i>(of SCAR Assignee)</i>	X			
CAPA DETERMINATION <i>(by Waters SQE/ QE below. Ineffective SCAR with no CAPA issued should be justified)</i>		☐ No CAPA needed, SCAR Effective. ☐ No CAPA needed, justification in remarks. ☐ CAPA number: CAPA-_____.			
APPROVAL	Waters Supplier Quality / Quality Engineer	Req?	Name/ Title	Sign	Date
		X			
APPROVAL	Other	Req?	Name/ Title	Sign	Date
		☐			
FINAL APPROVAL	Waters Quality Manager / Designee)	X			
Remarks (if any): ☐ Isolated occurrence of effectiveness fail. SCAR shall be revised and submitted before due date.					