

Audit Nonconformity (ANC) Number <i>XNC-SGYYMMNN</i>	INC-SG200702	Assignee, Company <i>(Supplier designated point of contact or WPPL Auditee)</i>	Luo Hua Zhen, WPPL (Test Engineering Operations)
SECTION 1: INTRODUCTION <i>(To be completed by Waters Supplier Quality / Quality Engineer)</i>			
Category	☐ CNC ☐ MNC ☒ NC	Failure Type	Facility & Equipment Controls
Statement	There are multiple inaccuracies observed in the calibration records provided by Micro Precision Calibration.		
Requirement <i>Standard, regulation or document that is not met</i>	ISO9001:2015 Cl. 8.4 Control of externally provided processes, products and services. 8.4.1 The organization shall ensure that externally provided processes, products and services conform to requirements.		
Objective Evidence	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# 122994G, 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 <i>(Waters Supplier Quality / Quality Engineer)</i>	Name/ Title	Sign	Date
	Bayu Darmawan/ ISO Consultant	Refer to issued copy	Refer to issued copy
Issuance Date	Due Date for Sections 2 and 3 <i>(Should be within 90 days from issuance.)</i>	Due Date for Section 2 <i>(Should be within 21 days from issuance for internal NC and MNC; 3 days for Internal CNC.)</i>	Remarks (if any): Refer to issued copy
See attach	See issued copy	☐ N/A, Supplier Audit Nonconformity	
SECTION 2: ROOT CAUSE ANALYSIS AND INTERIM CONTAINMENT ACTIONS			
SECTION 2A: FORM A TEAM <i>List Team Members' Names/ Function (minimum 2 personnel)</i>	Luo HuaZhen (Senior Test Engineer); Desmond Ann (Manufacturing Team Lead), Eugene Lim (Manufacturing Engineer), Siddharth Udayshankar (Product Assurance Engineer)		
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>			Completion Date <i>(DD.MM.YY)</i>
1. Review of calibration records from Jan 2019 to Jul 2020. Result of review: inaccuracies found in calibration reports (certificate numbers: 551220083507606, 551220083694795, 551220083694803, 551220083477955). Refer to Attachment INC-SG200702-01. For full list of calibration reports (Flex Singapore; Venture Singapore; CEI Singapore; Flex Senai, CEI Batam, WPPL). Refer to Attachment INC-SG200702-02 for MasterList. 2. Review of calibration sticker against calibration report for equipment in WPPL. Result of review: All calibration required equipment has been reviewed. No issue was highlighted. Refert to Attachment INC-SG200702-03 for review checklist.			17.07.20 28.07.20
SECTION 2C: ROOT CAUSE ANALYSIS (RCA) AND RISK ASSESSMENT <i>(Objective evidence should be attached and referenced with running number e.g. Refer to Attachment 1).</i>			
1. Calibration Service Provider's error in generation of calibration report. Refer to SCAR-SG200701. 2. Review of calibration report by Contract Manufacturer did not effectively detect inaccuracies. 3. Calibration Service Provider's error in QC check of calibration sticker against calibration certificate. Refer to SCAR-SG200701.			
RCA Category	Facility & Equipment Controls	Sub-Category	<i>Select from Dropdown</i>
RCA Category 2 (if any)	<i>Select from Dropdown</i>	Sub-Category 2 (if any)	<i>Select from Dropdown</i>
SECTION 2D: PLAN OF PERMANENT CORRECTIVE ACTION(S) <i>(Each root cause in section 2 shall be addressed. Documentation shall be updated as appropriate. Where applicable, Part Number(s), Part Description(s), Quantities, Action Owner should be included).</i>			Plan Date <i>(DD.MM.YY)</i>

1. Refer to SCAR-SG200701. 2. Reemphasize to Flextronics to ensure calibration reports are reviewed for conformity to requirements. 3. Reemphasize to Operations' Calibration Coordinators/ Designee to ensure that review of calibration report includes review of label against calibration certificate per WPPL-WI-05 Section 8.3.4.				1. 14.07.20 2. 23.07.20 3. 23.07.20	
SECTION 2E: PLAN ACTION(S) TO PREVENT RECURRENCE <i>(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).</i>				Plan Date (DD.MM.YY)	
1. Reemphasize to wider Global Operations team and other Contract Manufacturers (Venture; CEI Singapore) to ensure calibration reports are reviewed for conformity to requirements. 2. Standardize the notes template for Calibration Service Provider. 3. Create separate account for Calibration Service Provider for individual Contract Manufacturer to eliminate need to customize calibration location.				1. 23.07.20 2. 23.07.20 3. 31.08.20	
SUBMISSION BY <i>(by Audit Nonconformity Assignee)</i>		Req?	Name/ Title	Sign	Date
		X	Luo HuaZhen		
RCA APPROVAL	Quality Manager/ Quality Supervisor <i>(of Assignee)</i>	X			
	Waters Supplier Quality / Quality Engineer	X			
	Other	☐			
Remarks (if any): Certain calibration reports states calibration location as "calibration performed at customer's facility" with remarks such as "calibrated at Flextronics" or "calibrated at Venture". This was deemed acceptable by team as contract manufacturers were deemed indirect customer of MPC. Control of Monitoring and Measuring Equipment shall be included in the audit planning for CMO audits.					

SECTION 3A: IMPLEMENTATION OF PERMANENT CORRECTIVE ACTION(S) <i>(Attach evidence)</i>				Completion Date (DD.MM.YY)
1. Refer to SCAR-SG200701. Please refer to attachment INC-SG200702-04 for SCAR-SG200701. 2. Reemphasize to Flextronics to ensure calibration reports are reviewed for conformity to requirements. Please refer to attachment INC-SG200702-05 for reemphasize training list. 3. Reemphasize to Operations' Calibration Coordinators/ Designee to ensure that review of calibration report includes review of label against calibration certificate per WPPL-WI-05 Section 8.3.4. Please refer to attachment INC-SG200702-06 for re-training records				1. 14.07.20 2. 23.07.20 3. 23.07.20
SECTION 3B: ACTION(S) TO PREVENT RECURRENCE <i>(Attach evidence)</i>				Completion Date (DD.MM.YY)
1. Reemphasize to wider Global Operations team and other Contract Manufacturers (Venture; CEI Singapore) to ensure calibration reports are reviewed for conformity to requirements. Please refer to attachment INC-SG200702-07 for training records. 2. Standardize the notes template for Calibration Service Provider. Please refer to attachment INC-SG200702-08 for communication notes. 3. Create separate account for Calibration Service Provider for individual Contract Manufacturer to eliminate need to customize calibration location. Please refer to attachment INC-SG200702-04 for SCAR-SG200701.				1. 23.07.20 2. 23.07.20 3. 31.08.20
SUBMISSION BY <i>(by Assignee)</i>		Name/ Title	Sign	Date
		Luo HuaZhen		02 Sep 2020

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 (DD.MM.YY)
N/A			N/A
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 (Pass/ Fail)	
1. Reviewed calibration certificate for standardized the notes template.	1. Standardized the notes template for Calibration Service Provider is implemented	Pass, acceptance criteria met.	

2. Reviewed calibration certificate under sperate account with recommended address formort.		as per request. Please refer to sample check as attachment INC-SG200702-09.			
		2. Certficate under separate account is updated per recommended address format. Please refer to sample check as attachment INC-SG200702-10			
Remarks (if any): ☐ Attached extension request WPPL-FM-25. N/A					
SUBMISSION BY (by Assignee)		Req?	Name/ Title	Sign	Date
		X	Luo HuaZhen/Sr Test Engineer		29 Sep 2020
APPROVAL	Quality Manager/ Quality Supervisor (of Assignee)	X	Tan Kah Chin/ Sr QA Manager		
	Management Rep/ QMS In-Charge (of Assignee)	X	Jen Chen/Sr Quality Engineer		
CAPA DETERMINATION (by Waters SQE/ QE below. Ineffective actions with no CAPA issued should be justified)		☐ No CAPA needed, Actions Effective. ☐ No CAPA needed, justification in remarks. ☐ CAPA number: CAPA-_____.			
APPROVAL	Waters Supplier Quality / Quality Engineer	Req?	Name/ Title	Sign	Date
		X	Jen Chen/Sr Quality Engineer		
APPROVAL	Other	☒	Edwin Koh/Sr Ops Manager		
FINAL APPROVAL	Waters Quality Manager / Designee)	X	Tan Kah Chin/ Sr QA Manager		
Remarks (if any): ☐ Isolated occurrence of effectiveness fail. ANC shall be revised and submitted before due date. N/A					