

Originator	Ernest Chua	Title	Process Validation Engineer	Phone	7120	Date	22 Jan 2021
System Model	TE0084050	System Name	CPSM Final Test System				
Install Location	Venture, Singapore	Install Site	Production Area				
System Purpose	System facilitates the functional test of FTN, FL, and ARC sample managers. System downloads firmware, verifies electrical connection and assembly, performs various calibrations, verifies functional mechanical performance and assembly, and verifies chemistry performance.						
System Design	The system is custom equipment designed by Test Engineering and includes a computer, touch screen monitor, cable interface box, BSM, TUV, and column manager. TE0084050 is an update to TE83064; TE83064 systems will be converted using existing system components when possible.						
Timeline:	Q1-2021 is the target to convert TE83064 systems to TE0084050 systems						
Specifications	The associated design documents for TE0084050 can be found at TE0084050EQ, TE0084050ME, and TE0084050SF in SAP.						
Documentation	The associated TSP for this system can be found at 735002984 in SAP.						
Quality Risk Assessment: Does the equipment, method, and/or process considered to have minimum effect on the final product? Is the critical functionality of the final product of this equipment, method, and/or process adequately tested during later production steps?						Yes	No
						☐	☒
						☐	☒
An answer of "No" to both questions requires qualification per 730001835, Process Validation Procedure. An answer of "Yes" to either question identifies low risk to product quality and requires justification below: Note: A response of "Yes" to one or both questions may still result in qualification activities.							
This system will be validated according to the Process Validation Procedure 730001835.							
Comments	This form is for the installation of eight (8) CPSM FTN testers: TE84050-13, TE84050-14, TE84050-15, TE84050-16, TE84050-17, TE84050-18, TE84050-19 and TE84050-20.						

TO BE FILLED OUT BY SITE VMP COORDNATOR

Assigned TE or VAL Designator(s):

Responsibility	Name	Title	Signature	Date
Originator	Ernest Chua	Process Validation Engineer		25 JAN 2021
VMP Coordinator	Chan Yee Hwa	Manufacturing Engineer		29 Jan 2021