

Validation Master Plan Submission Form

Originator	Tyler Modelski	Extension	3549	Date	30-Mar-2018				
Equipment No.	TE0084040-1	Equipment/Process Name	MSV Leak Test System						
Plant Location	34 Maple St, Milford, MA		Area of Manufacturing	White Room					
Please describe the function of the Equipment, Method and/or Process.									
This equipment measures the leak rate of all three port to port fluidic paths in the Metering Syringe Valve Assy. After test this assembly is installed into all sample manager products and shipped as spares.									
Please describe if the Equipment, Method and/or Process have been custom designed or purchased?									
This is custom designed test equipment and has custom test software.									
When does this Equipment, Method and/or Process need to be used for production?									
April 2018									
Have any associated documents (Operating Procedure, TSP, ASP, MPR, Cal/PM, etc.) been written or received?									
MSV Performance Specification is written but not approved, TSP is written but not approved, CAL/PM is in process									
Is this Equipment, Method and/or Process considered to have minimum effect on the final product?					<table border="1"> <tr> <td>Yes</td><td>No</td></tr> <tr> <td>☐</td><td>☒</td></tr> </table>	Yes	No	☐	☒
Yes	No								
☐	☒								
Is the critical functionality of the end product of this Equipment, Method and/or Process adequately tested in later production steps?					<table border="1"> <tr> <td>Yes</td><td>No</td></tr> <tr> <td>☒</td><td>☐</td></tr> </table>	Yes	No	☒	☐
Yes	No								
☒	☐								
The critical functionality of the MSV is tested in CPSM Final Test and Acquity Sample Manager final test through a static pressure decay test and precision/linearity chemistry testing. The MSV leak test system is dynamic and more accurate than static leak decay testing. It is responsible for identifying machining errors/ improperly assembled valves prior to final test and the verification of spare valves that will be shipped to the field.									
Comments (optional)									
They are cutting an order for 500 Valves by end of April in support of the Bifrost project.									
This section to be complete by VMP coordinator									
The Equipment, Method and/or Process is added to the VMP and qualification deliverables will reside in the following SAP directory:									

Responsibility	Name (Print)	Title	Signature	Date (DD-MMM-YYYY)
Originator	Tyler Modelski	Test Validation Engineer II		30 Mar 2018
VMP coordinator	Tetiana Morse	Senior Process Validation Engineer		13 Apr 2018