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To Whom This May Concern:

The purpose of this letter is to inform potential users of the Stellant Multi-Patient (MP) System[1] that Bayer meets fluid path contamination resistance and cross contamination resistance requirements when used according to its instructions for use (IFU).

The Stellant MP System set has been designed, tested and manufactured to prevent fluid path contamination and cross contamination over the product's specified use life. This is accomplished with the use of two check valves and a length of tube in the single patient disposable set (SPDS) to isolate the multi-patient disposable set (MPDS) from the patient connection.

Testing has confirmed that the Stellant Multi-Patient System did not exceed the contamination index limit set forth in the product design requirements. Additionally, testing of the SPDS check valves (crack pressure, back pressure resistance and burst strength) was completed to ensure product function over the specified use life.

See page 2 for an overview of test results.

Best Regards,

Christopher Lazzara
Global Brand Director, CT

1 - Syringe Kit: Multi-patient Cat# SDS MP1 and Single Patient Disposable Cat#: SPD 250

Overview of Testing:

Fluid Path Contamination in Use Test Results:
This requirement was demonstrated by subjecting Stellant MP to simulated use in an environment with no extraordinary contamination control measures. The results show no evidence of detectable bacterial or fungal growth in fluid delivered from the MPDS at the end of its specified use life.

Cross Contamination Test Results:
This requirement was demonstrated by the following test of the SPDS. A viral load of approximately 1 billion (9 log10) plaque forming units was placed at the patient connection for one hour. No detectable viral contamination at the connection point to the MPDS was present after one hour exposure. The typical detection limit for viral tests is 1.67 pfu/ml. Therefore, no detection within a 0.5 ml titer corresponds to a demonstrated isolation of 8.7 to 9.7 log10.

SPDS Check Valve Performance Test Results:
Crack Pressure: The check valve crack pressure was confirmed to be between 1-7 psi over the product's specified use life.

Back Pressure: Testing demonstrated that the back pressure resistance of SPDS check valves exceeds 45 psi over the product's specified use life. This provides considerable margin when compared to patient blood pressure.

Burst Strength: The check valve burst strength was confirmed to be greater than 355 psi over the product's specified use life. The maximum injector pressure limit is 325 psi.