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Machine Solutions Inc. Chooses PROTOMED SA to Strengthen its Validation Test Services in the US

Machine Solutions Inc. and PROTOMED SA have signed an exclusive distribution agreement to bring world class product testing expertise to US customers. Machine Solutions Inc. will use PROTOMED SA to add hydrodynamic performance and high-end interventional device testing to its portfolio and extend its test services offer in the area of heart valve hydrodynamic performance validation, continuous flow particulate counting, fatigue and interventional device performance testing in compliance with FDA GLP guidelines.

"We have chosen to combine our services with MSI's existing test offer to act as a single source to test any interventional devices. PROTOMED is a fully integrated laboratory which gathers most medical device test needs in one single location. Test integration reduces overall R&D cost, optimizes the use of test resources and will most likely accelerate R&D development cycles." says Frédéric MOURET, President & CEO of PROTOMED SA.

"Machine Solutions Inc. is proud to strengthen its offer in product testing with PROTOMED SA. PROTOMED SA device testing expertise will increase our current testing capabilities on our IDTE and further expand our reach into areas such as heart valves testing and any interventional device testing requiring hydrodynamic testing capabilities." says Daniel KASPRZYK, CEO of Machine Solutions Inc.

PROTOMED SA uses a proprietary and validated dual chamber pulsatile tester to assess heart valve hydrodynamic performance. Stroke volume, heart rate and diastolic and systolic pressures can be easily modified to customer's requirements. The repeatability of measurements is ensured by a servo-control, which also monitors pressure and flow waveforms. The plexiglass visualization box, surrounding silicon made anatomical cavities (left atrium and ventricle, aorta), allows assessment of velocity fields using Particle Image Velocimetry. Echo Doppler is used to verify Bernoulli's equation.

Acute coating durability of polymer-coated devices under simulated use conditions can be performed directly with the Interventional Device Testing Equipment (IDTE) 2000 from Machine Solutions Inc. The IDTE 2000 uses a multi channel continuous flow particulate counting system to automatically measure and display particulate contamination levels in the circulating solution at each step of the device deployment procedure. Particulate release measurement is designed to specifically provide ongoing measurement during device simulated use. Particles are continuously monitored, counted and classified according to size. Background noise assessment and spiking/recovery studies are performed to measure particulate level prior to device deployment. Particulate measurement is performed in accordance to both existing and future standards.

About PROTOMED

PROTOMED SA, FRANCE, provides medical device companies with the best mechanical test practices in the industry. Our ISO 9001 & 13485 certified services help device manufacturers meet the highest standards in the industry in support of FDA submission and CE mark certification. PROTOMED offers turnkey test solutions for companies developing implantable and interventional cardiovascular devices.

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About Machine Solutions Inc.

Machine Solutions Inc. is a leading manufacturer and pioneer in providing the medical device community with the premier solution for catheter processing applications. MSI has been instrumental in automating or semi-automating several manual processes within catheter manufacturing organizations. Please visit www.machinesolutions.com for additional corporate and MSI product information.

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