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VentureMed Group Receives European Medical Device Regulation (MDR) Certification for FLEX Vessel Prep™ System

Minneapolis, Minnesota, September 6, 2023 - VentureMed Group, Inc., a privately held medical device innovator in access management for arteriovenous (AV) fistulas and grafts and vessel preparation for interventional treatment of peripheral arterial disease (PAD) announced today that the company is an early recipient of MDR certification. Gaining MDR certification ensures the FLEX device is in alignment with described requirements and conformity assessment procedures that must be met before medical devices are introduced into the European Economic Area.

"CE Mark under these new requirements is more stringent than the CE Mark under the Medical Device Directive and is focused on quality as well as patient safety. This significant achievement is a testament to our company's dedication to provide the safest and highest quality products for our customers and their patients," commented Jill Schweiger, VentureMed's VP of Clinical, Regulatory, and Quality.

"MDR certification demonstrates our commitment to quality and will enable continued commercial expansion of the FLEX Vessel Prep System into the CE marked geographies." said Denis Harrington, VentureMed's President and CEO.

About VentureMed Group, Inc. and the FLEX Vessel Prep System

VentureMed Group, Inc. develops and markets innovative endovascular medical devices to solve unmet medical needs in the treatment of stenoses of AV fistulas and grafts and PAD. The FLEX VP™ System is a unique, non-balloon-based approach to optimizing revascularization. FLEX creates controlled-depth micro-incisions, releasing circumferential tension that may lead to improved vessel compliance, enabling luminal gain at lower pressure and with less vessel trauma, which may help limit restenosis. FLEX was designed to provide controlled and predictable pre-treatment to optimize outcomes in complex stenoses & lesions of any length or vessel morphology. The FLEX VP System received CE Mark and 510(k) clearance from the US Food and Drug Administration.

For more information, visit www.VentureMedgroup.com.