werfen

Press Release

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WERFEN RECEIVES US FDA 510(K) CLEARANCE FOR ROTEM® SIGMA THROMBOELASTOMETRY SYSTEM

— Enables Rapid Assessment of Critical Bleeding at the Point of Care, Reducing Inappropriate Transfusions and Improving Outcomes—

Bedford, MA, July 18, 2022—Werfen today announced the 510(k) clearance of the ROTEM *sigma* Thromboelastometry System by the US Food and Drug Administration (FDA). The ROTEM *sigma* delivers real-time, rapid and actionable results, now at the point of care (POC), to guide bleeding management. With clinical use throughout Europe, Australia, Asia, Latin America and Africa, the ROTEM *sigma* will be commercialized in the US in late 2022.

Built upon proven cup-and-pin technology, the ROTEM *sigma* leverages similar assays as its leading predecessor, the ROTEM *delta* Thromboelastometry System, used widely throughout North America and in thousands of peer-reviewed clinical studies. For a clear picture of coagulopathy, the ROTEM *sigma* provides at-a-glance assessment of clot firmness and stability, enabling hemostasis optimization, while minimizing blood loss. The result is a reduction in inappropriate transfusions, associated complications and cost—all essential to a successful patient blood management (PBM) program.

"Reducing inappropriate transfusions is paramount in healthcare today for patient safety, to help preserve blood supply, and for cost containment. Incorporating ROTEM *sigma* testing into a PBM program allows hospitals to achieve these goals," said Remo Tazzi, VP, Worldwide Marketing and Service, Hemostasis and Acute Care Diagnostics at Werfen. "By viewing real-time, actionable results in the operating room, surgeons, anesthesiologists, and other clinicians can make faster and more informed transfusion decisions, improving patient outcomes and enhancing hospital efficiency."

ROTEM *sigma* is fully integrated and automated, cartridge-based, and simple to operate, making it ideal for POC testing. Large, easy-to-view TEMograms provide clear, real-time viscoelastic testing results, for enhanced, rapid interpretation. With a comprehensive assay menu, and four independent channels, the ROTEM *sigma* facilitates targeted therapeutic decisions in a variety of clinical settings. For critical procedures, including those requiring heparin neutralization, the ROTEM *sigma* complete + hep cartridge delivers intraoperative results in the cardiovascular surgery and liver transplantation.

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Citrated whole blood arterial or venous samples require no incubation time and testing is initiated in minutes. Early validated parameters, such as A5, are delivered faster than traditional methods, with actionable results in less than 15 minutes—essential in critical bleeding scenarios. Ready-to-use, room-temperature cartridges with integrated closed-tube sampling simplify testing, saving time and standardizing the testing process.

Werfen's new GEMweb Live real-time onscreen viewer consolidates diagnostic test results from ROTEM Thromboelastometry Systems, as well those from other networked systems in Werfen's portfolio of Acute Care Diagnostics (ACD) systems. Comprehensive, rapid test results, viewed on one screen, help guide goal-directed therapy and other critical intraoperative needs, before, during and after surgery, enabling faster clinical decision-making during cardiac surgery. Additionally, GEMweb Plus 500 Custom Connectivity provides centralized access to results from any networked Werfen ACD system, including ROTEM *sigma*.

About Werfen's Acute Care Diagnostics Portfolio

The ROTEM *sigma* Thromboelastometry System is part of Werfen's integrated and comprehensive ACD product portfolio—helping clinicians and laboratorians achieve better patient outcomes, lower total cost of care, assure accreditation compliance and improve operational efficiency in hospital acute care settings. For Whole Blood Hemostasis testing, ROTEM thromboelastometry systems, the GEM Hemochron™ 100 system, and the VerifyNow™ platelet-reactivity testing system inform key clinical decisions regarding transfusion, bleeding risk and heparin dose adjustment during surgical and interventional procedures along with a clinical assessment of the patient's condition and other laboratory tests. For Blood Gas testing, the GEM Premier systems, including GEM Premier 5000 and 3500 systems, and Avoximeter™ portable CO-Oximeters, simplify POC operations by automating key labor- and skill-intensive tasks, including quality management and system maintenance. From Cardiovascular Operating Rooms and Catheterization Labs, to Intensive Care Units and Emergency Departments, whole-blood, cartridge-based systems with Werfen's integrated data management solutions, help hospitals improve efficiency and enhance patient care.

Werfen (www.werfen.com), founded in 1966, is a worldwide developer, manufacturer and distributor of specialized diagnostic instruments, related reagents, automation workcells, and data management solutions for use primarily in hospitals and independent clinical laboratories. The Company's business lines include Hemostasis, Acute Care Diagnostics (ACD), Autoimmunity, and Original Equipment Manufacturing (OEM). Werfen's Hemostasis portfolio includes ACL TOP® Family 50 Series and ACL TOP Family Hemostasis Testing Systems, ACL AcuStar® system, ACL Elite® systems, HemoCell™ Specialized Lab Automation, HemoHub™ Intelligent Data Manager, along with the comprehensive line of HemosIL® assays. The ACD portfolio includes the GEM® Premier™ 5000 system with Intelligent Quality Management 2 (iQM®2), GEM Premier 3500 system with iQM, GEM Premier ChemSTAT™ system, ROTEM® Thromboelastometry Systems, Hemochron™ systems, VerifyNow™ platelet function testing system, and Avoximeter™ CO-Oximeters, GEMweb® Plus Custom Connectivity and GEMweb Live. The Autoimmunity portfolio includes Aptiva®, BIO-FLASH®, NOVA View®, AUTOLoader and QUANTA-Lyser® 3000 systems, and QUANTA Link® data management solutions. The OEM business line offers services for end-to-end development and manufacturing of customized immunoassays and biomaterials for diagnostic companies.

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