Diagnostica Stago Inc.
Five Century Drive
Parsippany, NJ 07054 • USA

+1 973 631 1200 • +1 973 631 1618
general.info@stago-us.com
www.stago-us.com

Press Release

Contact:
Nichole Howard
Diagnostica Stago, Inc.
nichole.howard@us.stago.com

FOR DISTRIBUTION MONDAY, July 10, 2023

Diagnotica Stago's Max Generation coagulation systems receive Department of Defense Health Agency Authorization to Operate

Parsippany, NJ, July 10, 2023 – Diagnostica Stago, Inc. (Stago), a global leader in hemostasis testing, announced it received an Authorization to Operate from the Department of Defense Health Agency (DHA) for the company's Max Generation analyzers and middleware solution. The DHA Cybersecurity Logistics (CyberLog) ATO Assess and Incorporate (A&I) process is based on the National Institute for Standard and Technology (NIST) Risk Assessment Framework and is considered to have very stringent cybersecurity requirements.

Authorization to Operate (ATO) cybersecurity clearance allows all US DoD Military Treatment Facilities worldwide to purchase and connect Stago Max Generation systems to the DHA network. The ATO A&I multi-phase process includes a series of software scans, Security Technical Implementation Guide reviews, and virtual meetings with CyberLog to assess the security of the systems provided to military facilities. Over the last year, Stago cybersecurity experts, software development, and product management teams successfully worked with CyberLog in an extensive review of the applications incorporated with STA R Max®, STA Compact Max® and STA Coag Expert®.

"With the number of cybersecurity attacks on healthcare facilities increasing every year, Stago remains fully committed to develop software security features that meet the most stringent cybersecurity requirements," says Emmanuel Vieux, Stago Executive Director of Industrial and Supply Chain. With ATO, Military Treatment Facilities can purchase and quickly connect Stago Max Generation systems to the DHA network. Stago will continue to collaborate with DHA's Continuous Monitoring program to maintain ATO acceptance for the Max Generation analyzers and data management systems.

Philippe Barroux, CEO, Stago North America, says, "Receiving the ATO demonstrates to customers that we are committed in providing the highest quality hemostasis products with software applications that pass some of the most stringent security requirements. We are proud to deliver our products and services to military personnel throughout the US and beyond."

About Stago

International, independent, and privately-owned group established in 1945 in France, Stago is currently the only company in the In Vitro Diagnostics industry exclusively dedicated to the exploration of Hemostasis and Thrombosis.

With a staff close to 2,500 and the most advanced technologies, Stago designs, manufactures and markets the broadest range of reagents and analytical instruments in hemostasis worldwide. Stago offers consistent, high-quality solutions. Stago devotes its research and innovative skills to the development of increasingly effective medical diagnostic products and instrumentation.

The Group has R&D and Production units in France, the United States, the Netherlands, Germany, Ireland, and China and is ISO 13485, ISO 9001 (2008) certified. Its main reagent's production unit is also ISO 14001 certified.

A fully controlled activity

Stago brings together complementary expertise in clinical biology, chemistry, physics, mechanics, electronics, fluidics, optics, IT, statistics, and ergonomics.
The Company is committed to constantly improve its expertise by:

- keeping up with the latest technological, scientific, and medical developments,
- acquiring and integrating specialized companies: 1994→BioCytex (cellular Hemostasis) – 2009→Thrombinoscope and Synapse (Thrombin Generation) – 2017→HemoSonics (POC technology)
- strengthening its manufacturing capacity,
- using acquisitions to create synergy between R&D, Production and Supply Chain: 2010→ Trinity Biotech's coagulation business

With nearly 20% of its workforce dedicated to R&D, Stago is constantly innovating. The prospective research center and scientific collaboration with numerous university research teams result in leading scientific publications.