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NSF International Expands Medical Device Consulting Services in Europe With Purchase of PROSYSTEM AG

Acquisition of German consulting firm diversifies NSF International's medical device service offerings and provides greater access to Europe's growing and increasingly regulated medical device industry

ANN ARBOR, Mich., USA and HAMBURG, Germany — NSF International, a global public health and safety organization, recently completed the acquisition of PROSYSTEM AG, a German medical device consulting firm specializing in regulatory affairs and clinical evaluation. As part of NSF International's global medical device consulting business, the well-respected German company will be known as PROSYSTEM, an NSF International company.

Europe's US$101 billion medical device industry is expected to grow at a rate of approximately 10 percent per year while new regulatory requirements create significant opportunities for medical device consulting firms. New EU regulations for medical devices (MDR) and in-vitro diagnostic devices (IVDR) were published in May 2017, establishing new supply chain traceability requirements, new standards for clinical evidence and more rigorous reporting and post-market surveillance requirements.

The acquisition of PROSYSTEM expands NSF International's medical device business in Europe and positions the company to meet an increasing demand for medical device consulting, education and training services in the EU. Additionally, the acquisition provides NSF's global customers with a deeper knowledge of Europe's medical device industry and its changing regulatory landscape.

The PROSYSTEM acquisition also expands NSF International's medical device service offerings by adding medical device clinical evaluation, standards engagement and software development capabilities.

"The European medical device market is the second largest in the world, so it is very important for our global clients selling products in the EU," said Elaine Messa, President of medical device consulting services at NSF International. "The talented team at PROSYSTEM will help NSF International better serve global clients while also enhancing our services to clients doing business in Europe."

Founded in 1999 by the late Dr. Jürgen Stettin and Oliver Christ, PROSYSTEM specializes in risk management, quality management, regulatory affairs and clinical evaluations for the medical device industry. The company also provides a variety of other services, including education and training, project management, usability assessments and ISO standards support services.

PROSYSTEM employs 35 people, most located in Germany, and operates offices in Germany, Switzerland, Brazil and the United States. PROSYSTEM employees will join NSF International's approximately 2,730 employees working in 33 countries around the world. The company's co-founder, Oliver Christ, will join NSF International as Executive Vice President reporting to NSF International's Elaine Messa. Randolph Stender will join NSF International and retain his current title of General Manager of PROSYSTEM.

PROSYSTEM clients will benefit from NSF International's vast regulatory and technical expertise, global consulting network and expanded range of services. Many of NSF International's medical device experts are former U.S. FDA regulators with deep knowledge of U.S. and international medical device regulations and standards, including the international Medical Device Single Audit Program (MDSAP). PROSYSTEM clients will also have access to NSF's many quality management and regulatory training courses, where they can learn from former regulators and industry experts.

Beyond medical devices, NSF International services include testing, auditing, certification, training and education, and consulting for the global pharma biotech, dietary supplement, food safety, water quality and environmental sectors. Additionally, NSF International will provide the global resources and systems necessary for PROSYSTEM to grow and meet almost any client need.

"This acquisition makes sense on many different levels for both NSF International and PROSYSTEM," said Oliver Christ, Executive Vice President of PROSYSTEM, an NSF International company. "Both organizations approach the medical device industry from a scientific, public health perspective and both adhere to the highest quality standards. As an NSF International company, we will be able to grow our operations, enhance technologies and serve PROSYSTEM's clients in exciting new ways, helping them navigate the changing regulatory environment in Europe."

Oliver Christ is well known in the global medical device community. He is an active member of many international standardization committees such as ISO TC210/JWG1 on ISO 14971, ISO TC215/JWG7 on IEC 80001-1 and IEC TC62/WG on IEC 60601-1 3rd/A2.

Visit NSF's medical devices website for more information about NSF International medical device services or contact medicaldevices@nsf.org.

Editor's notes:

- European media seeking additional information or interviews can contact NSF International's Howard Broadbridge at hbroadbridge@nsf.org or +44 (0) 7889 810328.
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NSF International (nsf.org) is a global independent organization that writes standards, and tests and certifies products for the health sciences, water, food and consumer goods industries to minimize

adverse health effects and protect the environment. Founded in 1944, NSF is committed to protecting human health and safety worldwide. With clients in more than 170 countries, NSF International is a Pan American Health Organization/World Health Organization (WHO) Collaborating Center on Food Safety, Water Quality and Indoor Environment.

NSF International's medical device services include comprehensive consulting, training and education, and testing solutions to assist medical device companies in navigating international regulatory hurdles throughout the total product lifecycle. Beyond medical devices, NSF's health sciences services include training and education, consulting, auditing, DNA testing, certification, R&D, regulatory guidance and corporate compliance for the pharma biotech, dietary supplement and bottled water/beverage industries throughout the product lifecycle.