ISEMED and Arazy Group sign agreement for advanced regulatory affair technology

Global market access is now available to the Italian Medtech and IVD industry using advanced regulatory affair technology and management platforms.

ISEMED (Imola, Italy) had signed a representation agreement with Arazy Group Consultant (Vancouver, BC, Canada) to become the Italian representative of Arazy's advanced regulatory affair technology, SaaS system, and software specifically designed for medical and IVD device manufacturers.

Arazy Group Consultants Inc is a leading Medtech and IVD regulatory affairs firm with 26 years of experience. The company's HQ is in Vancouver, BC, Canada, and it provides services in over 140 counties worldwide.

The company developed propriety regulatory affair technology, LICENSALE – Global MedTech Registration Management System, and REGISLATE – Medtech Regulatory Management Software, allowing Medtech manufacturers to obtain regulatory information, expert support, and manage their product registration processes all over the world. The platform has been used by thousands of small to multinational companies since 2013, and it has been shown to provide market access faster and more efficiently than any other practice.

"*ISEMED focus has always been to help the Italian medical device and IVD manufacturers to succeed and grow by extending to global markets access and had been offering registration services in foreign markets for the local industry*," - says Guido Bonapace, founder and CEO of ISEMED. "*Modern regulatory affairs practices are essential to the Italian MedTech companies who wish to remain competitive in their global market while staying efficient with their regulatory resources, budget, and management. This knowledge and practice are now available for the Italian Medtech industry through Isemed and Arazy cooperation*."

"We are delighted to bring our service and technology to the Italian MedTech industry with a professional consulting company like ISEMED. " - says Benjamin Arazy, CEO and founder of the Arazy Group. "*There is significant uncertainty with obtaining or maintaining CE mark under the new regulations. Also, there is a lack of qualified regulatory human resources for both Notified Bodies and the industry. It creates a need for advanced solutions to provide faster, effective, and efficient global market access. We are confident that the Italian manufacturers will find our technology to meet their needs and the combined know-how and experience of both companies to exceed their expectations*."

About ISEMED

ISEMED, founded in 2008, is based on high professional competencies in technical, quality and regulatory affairs developed in both medical and industrial manufacturing companies as well as consultants for Notified Bodies. A continuous learning activity concerning Medical Devices, International Regulations and Technical Standards of its founder has been well recognized by Companies, Notified Bodies, International Education Societies and Bologna University. Today ISEMED is your best partner for developing a business plan on the international markets, considering all the mandatory steps in terms of time and cost-effectiveness.

Since July 2022, ISEMED is part of the Tentamus Group, a global network of specialized laboratories and service companies that works for quality and safety in the food, cosmetics, pharmaceutical and medical field. Please find further information at https://www.isemed.eu

Through cooperation with the Arazy Group, ISEMED can support the industries involved both in the Medical Device and IVD fields in order to help them increase the technical, economic, commercial and regulatory business development in more than 140 countries in the world.

For more details, please contact:

Italy: Claudia Bandini
Sales and Marketing
ISEMED
Tel: +39 0542 683803 (Internal code #210)
Cel: +39 342 0907968
E-mail: commerciale@isemed.eu