# TISSIUM

# TISSIUM Receives CE Mark and Announces Manufacturing Compliance Certification from TÜV SÜD

- Received CE Mark for its first sterile biodegradable sealant in a pre-filled syringe format
- Issuance of new certifications from TÜV SÜD for TISSIUM's innovative products

**Paris, France**, April 2, 2020—TISSIUM, a privately-owned life science company developing fully synthetic, biomorphic programmable polymers, announced the receipt of a CE-mark for its sterile biodegradable sealant in a pre-filled syringe. TISSIUM also announced the completion of the transfer of its ISO 13485:2016 compliance certificate that encompasses the design, development and production of its proprietary polymer-based devices and related accessories.

The TÜV SÜD certification is for the design, development and production of TISSIUM polymers for use in vascular reconstruction in accordance with European Union Directives on medical devices. This certification from TÜV SÜD, one of the few organizations that is a designated notified body under the new European Medical Device Regulation (MDR), enables TISSIUM to leverage its proprietary research, development and manufacturing platform for multiple new products addressing novel indications going forward. TÜV SÜD's MDR designation will also ensure the continuity of regulatory compliance and support post-MDR implementation.

"TISSIUM has been diligently working to achieve CE Marking for our products manufactured at our factory in Roncq.", said Christophe Bancel, CEO of TISSIUM. "This milestone continues to strengthen TISSIUM's position as the future leader in tissue reconstruction through our capacity to innovate, develop and manufacture state-of-the-art solutions for patients. We are excited to continue developing and manufacturing innovative medical devices using our proprietary platform of biomorphic programmable polymers."

## **About TÜV SÜD**

TÜV SÜD is a premium quality, safety, and sustainability solutions provider that specializes in testing, inspection, auditing, certification, training, and knowledge services. Since 1866, the company has remained committed to its founding principle of protecting people, property and the environment from technology-related risks. Headquartered in Munich, Germany, TÜV SÜD is represented in more than 1,000 locations worldwide. TÜV SÜD operates globally with a team of more than 24,000 multi-disciplinary experts recognised as specialists in their respective fields. By combining impartial expertise with invaluable insights, the company adds tangible value to businesses, consumers and the environment. The aim of TÜV SÜD is to support customers with a comprehensive suite of services worldwide to increase efficiency, reduce costs and manage risk. Visit www.tuvsud.com

# TISSIUM

### **About TISSIUM:**

TISSIUM is a privately-owned life sciences company based in Paris, France that is dedicated to the rapid development and commercialization of a unique biopolymer platform to address various unmet clinical needs.

The company's platform is based on a proprietary polymer family with unique properties including the ability to conform to, and integrate with, surrounding tissue to enable natural healing. Furthermore, the modular design of the polymers enables customization to match tissue-specific requirements for different therapeutic areas. The company also develops delivery and activation devices for enhanced performance and usability of its family of polymers.

The Company's technology is based on world-class research and intellectual property from the laboratories of Professor Robert Langer (MIT) and Professor Jeffrey M. Karp (Brigham and Women's Hospital), who co-founded the company in 2013. For more information, please visit: <a href="https://www.TISSIUM.com">www.TISSIUM.com</a> and @TISSIUMtech.

###

# PRESS CONTACTS

### Europe

Brice Epry – Chief of Staff Tel: +33 1 76 21 72 28 contact@TISSIUM.com
Twitter: @TISSIUMtech

U.S.

Marion Janic

Tel: +1 212 223 4017

mjanic@rooneyco.com