TIGR® Matrix Surgical Mesh obtains CE certification according to EU MDR

Uppsala 2021-12-24. **Novus Scientific, leaders in soft tissue regeneration, today announced that their innovative implant, TIGR Matrix Surgical Mesh, has obtained CE certification under the new Medical Device Regulation EU 2017/745 (MDR). The certification is a crucial regulatory milestone and makes TIGR Matrix one of few class III medical devices that have met the new, more stringent requirements.**

TIGR Matrix is an innovative surgical implant made from synthetic, resorbable polymers. Since its first market introduction it has been used to benefit patients in more than 20'000 general- and plastic surgery procedures involving repair and reinforcement of soft tissues such as breast reconstructions following cancer. It is designed to provide tissue support for over 6 months and degrade completely in 3 years.

The MDR, which replaces the Medical Devices Directive (93/42/EEC) and Active Implantable Medical Devices Directive (90/385/EEC) brings with it more scrutiny of technical documentation; it addresses concerns over the assessment of product safety and performance by placing stricter requirements on clinical evaluation and post-market clinical follow-up, and requiring better traceability of devices through the supply chain.

"We are proud that TIGR Matrix is one of only a few class III implants of its kind that already has obtained this essential certification." Says Henrik Magnusson Hjorth, CEO of Novus Scientific and co-inventor of TIGR Matrix. *"A lot of hard work went into the process of updating our processes and our technical documentation to meet the new tougher requirements. We are now in a very strong position which we will use to accelerate usage of TIGR Matrix and strengthen our position as best-in-class when it comes to resorbable implants for breast- and abdominal wall reconstruction."*

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About TIGR Matrix

TIGR® Matrix is the world's first long-term resorbable, 100% synthetic, surgical mesh. Its unique technology consisting of dual-stage degradation and full resorption, paired with ease of use, is a significant step forward in surgical mesh technology. Since it uses polymers common in medical devices since the 1970's, and is 100% synthetic, its components are more than well documented and clinically proven. With a growing body of published clinical evidence, TIGR® Matrix is being used in many applications, e.g. breast reconstruction and abdominal wall reinforcement.

About Novus Scientific

Novus Scientific started as a spin-off company from Radi Medical Systems, a renowned cardiovascular medical device developer and manufacturer with several market-leading products in its portfolio. Following the sale of Radi Medical Systems to St. Jude Medical, the owners started Novus Scientific and the product TIGR® Matrix saw the light of day. Novus Scientific now have a distribution network spanning the globe. Together with specialized staff, the company possesses over 20 years of experience in developing, manufacturing, and marketing resorbable medical devices.

Novus Scientific´s headquarters are located in Uppsala, Sweden the medical technology and pharmaceuticals capital of the Nordics.