Implantica receives MDR certification for RefluxStop™

Implantica AG (publ), a medtech company at the forefront of bringing advanced technology into the body, is proud to announce that it has received Medical Device Regulation (MDR) certification from its Notified Body, BSI, for the company and RefluxStop™.

The latest Notified Body survey published by the European Commission in July 2023 estimated that of 11,418 MDR applications, only 2,951 had successfully achieved MDR certificates. Implantica is in the top quartile of manufacturers achieving MDR certification for its products.

Implantica was granted the EU Quality Management System (QMS) certificate and the EU Technical Documentation Assessment Certificate confirming Implantica's QMS and the RefluxStop™ are compliant with the latest regulations and standards required for medical devices in Europe.

"Our EU-MDR certification is a reflection of Implantica's strong commitment to complying with the highest quality and regulatory standards for medical devices. Implantica is excited to meet this milestone, enabling us to continue to provide products to the EU to meet our patients' needs. I'd like to thank the team for this significant achievement in our ambition to develop Implantica to a leading medtech company," said Dr. Peter Forsell, CEO of Implantica.

About the European Medical Device Regulation (MDR)
The MDR (EU) 2017/745 came into effect in May 2021, replacing the former European Directives for medical devices. It is intended to establish a robust, transparent, predictable and sustainable regulatory framework for medical devices to ensure a high level of safety and health whilst supporting innovation. MDR has introduced more stringent requirements for technical documentation, clinical evaluation and post-market surveillance, plus supply chain traceability and unique device identification. It represents the biggest change in European medical device compliance standards in more than 20 years.

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Implantica is listed on Nasdaq First North Premier Growth Market in Stockholm.

The company's Certified Adviser is FNCA Sweden AB, info@fnca.se

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About Implantica
Implantica is a medtech group dedicated to bringing advanced technology into the

body. Implantica's lead product, RefluxStop, is a CE-marked implant for the prevention of gastroesophageal reflux that will potentially create a paradigm shift in anti-reflux treatment as supported by successful clinical trial results. Implantica also focuses on eHealth inside the body and has developed a broad, patent protected, product pipeline based partly on two platform technologies: an eHealth platform designed to monitor a broad range of health parameters, control treatment from inside the body and communicate to the caregiver on distance and a wireless energizing platform designed to power remote-controlled implants wirelessly through intact skin. Implantica is listed on Nasdaq First North Premier Growth Market (ticker: IMP A SDB). Visit www.implantica.com for further information.

About RefluxStop™

RefluxStop is a new innovative treatment that has the potential to spur a paradigm shift in anti-reflux surgery. It's unique mechanism of action differentiates it from standard of care and current surgical solutions. Existing surgical procedures and devices are focused on the Lower Esophageal Sphincter (LES) with a principal assumption that the LES is weak and or improperly functioning thereby not closing properly. These methods encircle the food passageway to support the LES's closing sphincter and are commonly associated with side effects such as swallowing difficulties, inability to belch and vomit and gas bloating.

In contrast, the RefluxStop device addresses acid reflux without affecting the food passageway.

The RefluxStop mechanism of action is focused on reconstructing all three components of the anti-reflux barrier, that if compromised could possibly result in acid reflux. It restores and supports the natural anatomical physiology of the body allowing the body to itself solve the problem with acid reflux.

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