

# Implantica Successfully Completes MDSAP Recertification Audit

**Implantica AG (publ.), a medtech company at the forefront of introducing advanced technology into the body, including the innovative RefluxStop® device for the treatment of acid reflux, a treatment field with over 1 billion sufferers, announces the successful completion of its Medical Device Single Audit Program (MDSAP) recertification audit, renewing certifications for Europe, the United States, Canada and Brazil.**

The audit was conducted last week by Implantica's notified body, BSI, reaffirming the company's commitment to maintaining the highest international standards in quality management and regulatory compliance. The MDSAP enables a single regulatory audit of a medical device manufacturer's quality management system to satisfy the requirements of multiple jurisdictions, streamlining global compliance efforts.

Applications for Canada and Brazil are planned for submission in 2026, following completion of the U.S. Food and Drug Administration (FDA) inspections at Implantica's Malta site and its manufacturing facilities.

Additionally, Implantica has received confirmation from the FDA that the upcoming inspections will proceed as scheduled, despite the ongoing U.S. government shutdown. However, the 100-Day Meeting has been rescheduled by the FDA and moved forward one week to Friday, October 10<sup>th</sup>, to ensure full attendance of all review personnel.

Dr. Peter Forsell, CEO and founder of Implantica, says, "Successfully completing the MDSAP recertification audit once again demonstrates Implantica's unwavering dedication to patient safety, product quality and regulatory excellence. As we continue to expand our global presence, maintaining world-class standards across every market is fundamental to bringing our breakthrough implantable technologies to patients in need."

This successful audit marks another important milestone for Implantica as the company continues to advance its mission of transforming the treatment of chronic health conditions through innovative smart medical implants.

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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](mailto: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](http://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. Longer established surgical options for GORD involve encircling the food passageway to support the lower esophageal sphincter's closing mechanism and are commonly associated with side effects such as swallowing difficulties, pain when swallowing and inability to belch and/or vomit.

In contrast, the RefluxStop® device treats the cause of acid reflux without encircling and putting pressure on the food passageway. It restores and maintains the lower esophageal sphincter in its original, natural position.

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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