

# Implantica has successfully completed ISO 13485 and MDSAP recertifications

**Implantica AG (publ), a med-tech company at the forefront of bringing advanced technology into the body, announces that after a successful recertification audit program, Implantica CE Reflux Ltd. has obtained renewed ISO 13485 Quality Management System (QMS) and Medical Device Single Audit Program (MDSAP) certificates from its notified body, BSI.**

The ISO 13485 recertification demonstrates that Implantica's quality management system complies with the recognized international standard for the design, development and distribution of medical devices, and the MDSAP recertification supports a medical device manufacturer's quality management system to satisfy the requirements of multiple regulatory authorities.

"These recertifications provide the necessary foundation for building the continued commercial success of RefluxStop™, our CE-marked implant that treats the cause of acid reflux and is designed to become the standard of care in a market with 1 billion sufferers. The entire process confirms the high compliance and regulatory standard that Implantica maintains and is a key achievement. Congratulations to the entire team at Implantica for their dedication and commitment to maintaining the highest level of quality standards and patient safety across the company," says Peter Forsell, CEO of Implantica.

## **For further information, please contact:**

Nicole Pehrsson, Chief Corporate Affairs Officer  
Telephone (CH): +41 (0)79 335 09 49  
[nicole.pehrsson@implantica.com](mailto:nicole.pehrsson@implantica.com)

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 has the potential to 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 energising 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.

## **Newsroom**

<http://www.implantica.com/media/media-kit>

## **ISO 13485 certificate**

<http://implantica.prod.waas.site/files/MD660600.pdf>

## **MDSAP certificate**

<http://implantica.prod.waas.site/files/MDSAP709255.pdf>

## **Product Pipeline**

<http://www.implantica.com/product-pipeline/prioritized-products/>

## **Technology Platform**

<http://www.implantica.com/innovations/technology-platform-overview/>

## **Media Contact:**

Implantica AG

Juanita Eberhart

VP Marketing

M: +1 925-381-4581

[juanita.eberhart@implantica.com](mailto:juanita.eberhart@implantica.com)