



## **PRESS RELEASE**

Zug, April 25<sup>th</sup>, 2017

### **Successful FDA inspection at Rontis Hellas medical device manufacturing site in Larisa, Greece**

Rontis Corporation S.A. proudly announces that its medical device manufacturing site of Rontis Hellas in Larisa, Greece has successfully passed the inspection by the US Food and Drug Administration (FDA).

The inspection, carried out by the FDA Consumer Safety Officer, Medical Device Specialist, lasted 4 days as initially planned, started on 27<sup>th</sup> March and concluded on the 30<sup>th</sup>. The inspection confirmed the site to be compliant with the principles and guidelines of FDA's Quality System/Current Good Manufacturing Practice regulations for medical devices (21 CFR Part 820) and no Form 483 observations were issued. At the closing meeting the inspector informed that she was satisfied with what she had seen and complimented Rontis on its Quality System, inspection organization and the knowledge and work ethic of its team members.

On the outcome of the inspection, Elena Panorgia, Rontis Corporation's QA/RA Manager, said "The inspection was triggered by our FDA's approved product Cronus HP - High Pressure Peripheral Balloon Catheter. It is an extremely satisfying result for our team and for our customers. The Rontis Team members have demonstrated their commitment and ability to meet the highest quality standards in the manufacturing of endovascular catheters".

John Xourgias, Rontis Corporation S.A. VP Manufacturing, said "We are very proud of the result achieved during this flawless FDA inspection. I am very satisfied that the FDA inspector reported no observations and I want to congratulate the entire team. This is another important step for our site in Larisa, Greece as it confirms our ability to comply with high engineering, manufacturing and quality standards across all the Rontis sites."

Efi Soultou, Rontis Corporation S.A. CFO/COO, said “Passing the U.S. FDA inspection with no observations demonstrated our commitment and ability to provide the highest quality services to the global life science community and confirms our reliability and credibility towards our business partners as well as the millions of patients that we proudly serve together.”

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For further information, please contact Rontis’ Corporate Communication Department at [media.relations@rontis.com](mailto:media.relations@rontis.com)

### **About Rontis Corporation**

Rontis is a privately-held specialty healthcare company, with its headquarters in Zug, Switzerland. It employs over 650 employees worldwide and is organized across 5 major divisions: Medical Devices, Pharmaceuticals, Infant Nutrition, Consumer Healthcare and Healthcare Services. It carries 30 years of experience within the wider Medical Device arena and the respective Division is active in R&D, manufacturing, marketing and international sales of its products & services. The Medical Devices Division is committed to the application of specialty minimally-invasive therapies for Interventional Cardiology & Radiology procedures by applying state-of-the-art methodologies in research & development and production.

**Rontis Hellas S.A.**, the Greek subsidiary of the multinational corporation - based in Athens - is among others the entity responsible for the operation of the medical devices manufacturing plant of coronary & peripheral products, located in the town of Larissa, Greece. A respectable part of the R&D department for this specific division is based there, along with 75 specialized professionals, who are involved in the production, testing and quality control of the said products.

For more information, you may visit [www.rontis.com](http://www.rontis.com)

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