

Granulox wound spray granted CE mark thanks to Diapharm

Georgsmarienhütte, Lübeck (Germany) 24 April 2012. With its wound spray Granulox, SastoMed GmbH has recently brought a new medical device to market. It improves oxygen supply to chronic wounds, using haemoglobin as the transporter. SastoMed has engaged Diapharm (www.diapharm.com) to perform the certification of the Class III medical device, and the outcome has been a great success: only 16 months elapsed between Day 1 and the granting of an EU-wide CE mark. This period of time was much less than originally expected. Looking forward, Diapharm will also be performing the legal role of manufacturer of the wound spray through its ISO 13485 certified subsidiary HÄLSA Pharma GmbH. Manufacturing and batch release of the medical device will take place under the HÄLSA quality management system. Granulox is on sale now.

Granulox wound spray new on the market

“This wound spray makes it possible to apply a known principle in an uncomplicated manner for the first time – both in hospitals and in an outpatient setting,” explains Michael Sander, Director of SastoMed GmbH. As a result of easier diffusion, the haemoglobin in the product transports oxygen from the air to the wound bed and improves oxygen supply. Certification as a Class III medical device has been particularly ambitious, emphasises Sander, whose company has obtained the world-wide patent rights and rights of sale for the technology: “We are grateful to Diapharm that market release in Europe has now come about so quickly.” The technology behind Granulox comes from Sangui Bio Tech. The efficacy of the physical process has been proven in clinical trials.

(approx. 1,620 characters)

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*Press releases from Diapharm and photo material in print quality may be downloaded from:
www.diapharm.com/pr.html*

Caption (*packshot_granulox_iso.png*)

Granulox is a new medical device for the care of chronic wounds. It is sold by SastoMed GmbH and Diapharm is assuming the legal role of manufacturer.

Background information: SastoMed

Founded in 2010, SastoMed GmbH is a global supplier of health products for wound care. It is a joint venture between SanderStrothmann GmbH and SanguBioTech GmbH. The company head office is in Georgsmarienhütte, Germany.

Background information: Diapharm

Diapharm is an international full-service provider to the healthcare industry. Founded in 1988, Diapharm supports pharmaceutical companies in all questions concerning regulatory affairs, medical & clinical development, quality management and business development. Its activities focus on the sectors of medicinal products, food supplements and dietetic food, medical devices and cosmetics. With about 100 employees in Germany, Austria, Romania and the United Kingdom, Diapharm is at the service of multinational companies as well as of recent start-ups and small to mid-sized businesses.
