Press Release

Sandvik Additive Manufacturing achieves ISO 13485:2016 medical certification for management system of titanium powder plant

New state-of-the-art powder plant for Osprey® titanium powder

The management system of Sandvik's new powder plant in Sweden, producing Osprey® titanium powders, has recently received the 'ISO 13485:2016' medical certification. This means it is now approved to produce powders for use in the additive manufacturing of medical applications.

"This standard will reassure our customers that Sandvik has the necessary quality management systems in place to meet the stringent requirements of the medical industry, says Keith Murray, VP and Head of Global Sales, Sandvik Additive Manufacturing.

Additive manufacturing (AM), also known as 3D printing, is already playing a significant role in the medical segment. With additive manufacturing, implants and prostheses can be manufactured directly from an individual patient's anatomical data. This allows these customized products to be manufactured quickly, significantly enhancing the healing process and improving the prognosis for the patient.

Sandvik's titanium powder plant, located in Sandviken Sweden, was inaugurated in the end of 2019, with more than 150 guests including end-users in key industries like aerospace and medical. Since then an extensive work has been ongoing to ramp-up the highly automated plant, finetuning the process and optimizing the powder to ensure the best possible consistency, morphology and quality required for additive manufacturing. As a result of this meticulous and structured work, the 'ISO 13485:2016' certification for medical was recently received, in August. Earlier this year, the same powder plant also achieved the prestigious 'AS9100D' aerospace certification.

"Achieving the ISO 13485:2016 medical certification will allow our medical customers to complete the necessary regulatory supplier approvals when bringing a medical application to market, utilizing Osprey® titanium powders from Sandvik," says Keith Murray, VP and Head of Global Sales at Sandvik Additive Manufacturing.

The properties of the metal powders used, directly impact the reliability of the performance of the AM-process, as well as the quality and performance of the finished product. This medical certification ensures that best practices and continuous improvement techniques – including the company's development, manufacturing, and testing capabilities – are leveraged during all stages of the powder lifecycle, resulting in a safer medical device.

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“In additive manufacturing it is essential to use high-quality metal powders with consistent quality, adapted to the different additive manufacturing processes. Sandvik’s highly automated manufacturing process ensures excellent consistency,” says Keith Murray.

COMPLETE TRACEABILITY – FROM TITANIUM SPONGE TO FINISHED POWDER

Product traceability is especially important in the medical industry. Sandvik offers a complete traceability for its titanium powder, made possible by having the full supply chain in-house – from titanium sponge to finished powder. The new titanium powder process uses advanced electrode induction melting inert gas atomization technology to produce highly consistent and repeatable titanium powder with low oxygen and nitrogen levels. The production facility also includes dedicated downstream sieving, blending and packing facilities – integrated through the use of industrial robotics.

The powder plant is located next to Sandvik’s additive manufacturing facility in Sandviken, Sweden, which includes all relevant metal additive manufacturing processes. This means that the company can tailor the powder to different printing processes, on the same site.

“Having atomized fine metal powders for more than 40 years, and supplying titanium to the medical and aerospace industries for decades, Sandvik is no stranger to powder atomization or the requirements of the most demanding industries,” says Keith Murray.

Titanium has exceptional material properties, being strong yet light and offering high levels of corrosion resistance. At the same time, it is biocompatible. However, the cost and complexity of machining from titanium billet have historically restricted its use. Additive manufacturing opens up new opportunities.

“Now we are one of few metal powder and additive manufacturing companies that holds both the AS9100D quality certification for aerospace and the ISO 13485:2016 certification for medical. This will facilitate many customer collaborations going forward. Imagine what 158 years of leading materials expertise can do for your additive process,” says Keith Murray.

Powder metallurgy is also labeled a ‘recognized green technology’ – and the net-shape capability of technologies like additive manufacturing not only means that material waste is minimized, but also that great energy efficiency can be achieved, by eliminating manufacturing steps.

The first two powders produced at the plant will be Osprey® Ti-6Al-4V Grade 5 and Osprey® Ti-6Al-4V Grade 23. Other alloys are available on request. In addition to the ISO 13485:2016 and AS9100D certifications, the new titanium powder plant is also certified according to ISO 9001, ISO 14001 and ISO 45001.

For further information: *www.metalpowder.sandvik or www.additive.sandvik*

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SANDVIK ADDITIVE MANUFACTURING

Sandvik Additive Manufacturing *has a world-leading position in metal powder with the widest range of AM-alloys on the market, and the company has also made sizeable investments into a wide range of AM printing technologies for advanced metal components since 2013. Adding 158 years of leading expertise in materials technology, 75 years in post processing methods like metal cutting, sintering and heat treatment, Sandvik has well-established and leading competence across the entire AM-value chain.*

*In 2019, Sandvik acquired a significant stake in **BEAMIT**, a leading European AM service provider with the largest printing facilities in Europe, and in August 2020 BEAMIT acquired 100% of **ZARE**, bringing together the two leading AM service bureaus in Europe – to create one of the largest AM service providers in the world – servicing the most demanding industries.*

***Sandvik AB** is a high-tech and global engineering group with approximately 40,000 employees and sales of approximately 100 billion SEK in more than 160 countries (2019). The company was founded in Sweden in 1862.*

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