

## **BBS completes final manufacturing steps for CE marking**

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**BBS – Bioactive Bone Substitutes, an innovator in orthobiologics, today announced that the company’s ARTEBONE® production line is ready for the audit required for CE marking. Following a successful audit, the certified production line will meet the regulatory requirements to manufacture a medical device in the European Union (EU). This is an important step towards obtaining the CE marking for the company’s first product, ARTEBONE® ready-to-use paste, during the first half of 2020.**

ARTEBONE® ready-to-use paste is manufactured at the company’s wholly-owned manufacturing plant in Reisjärvi, Finland. The ARTEBONE® production line comprises both custom-made and automated technique that has been refined and prepared to handle an upcoming commercial scale production. This production line has now cleared the validation step and awaits the CE marking required manufacturing audit to be performed by the accredited Notified Body.

Pekka Jalovaara, CEO of BBS, commented “For medical devices, a high-quality manufacturing process is of uttermost importance. We are therefore pleased to announce, to the best of our knowledge, that we have completed all the manufacturing steps necessary to ensure compliance with the CE marking standards and look forward to the audit.”

Previously, the manufacturing process for the reindeer bone protein extract used in ARTEBONE® has been GMP-certified (Good Manufacturing Practice) as well as authorized by the Finnish Medicine Agency (FIMEA). For the ARTEBONE® ready-to-use paste, the company anticipates that the CE marking will be obtained during the first half of 2020 with the product commercialization to follow thereafter.

### **Contact**

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### **About BBS – Bioactive Bone Substitutes**

BBS-Bioactive Bone Substitutes Plc is a leading orthobiologic biotech company with origins in Finland. The company’s technology, ARTEBONE®, is a next generation bone substitute that targets treatment of bone defects and healing problems in extremities such as hands and ankles, scapula and pelvis. Its superior properties stem from the natural growth factors extracted from reindeer bone combined with scaffold-providing TCP (tricalciumphosphate) granules and has the potential of transforming orthopedic surgery. The first product, ARTEBONE® ready-to-use paste, is complete and the application process for the CE marking enabling commercialization is in progress. BBS’ Certified Adviser at Nasdaq First North Stockholm and Helsinki is Stockholm Certified Advisers AB, +46 70 5516 729, [info@certifiedadviser.se](mailto:info@certifiedadviser.se). More information: [www.bbs-artebone.fi](http://www.bbs-artebone.fi).