

Press release

SmartBone[®] obtains CE marking renewals

Mezzovico-Vira, 26 February 2019 -SmartBone[®], the innovative bone graft by Industrie Biomediche Insubri SA (IBI SA), obtained the CE/EC marking renewals.

Following months of intensive activity, quality, safety and commitment have been rewarded: IBI obtained the renewals of CE marking on SmartBone[®] by UK Notified Body BSI. This confirms that SmartBone[®] as a medical device and its manufacturing process are fully compliant with all health and safety related quality assurance essential requirements for being put into the European economic area market.

“We are proud of this extremely important result we have achieved: the European regulatory framework demanded high efforts to IBI team ...” comments Federico Fumagalli, Chief Operating Officer, “...it is, indeed, thanks to our employees and their high professional competencies that we can keep offering our innovative solutions for bone regeneration to our customers and patients. This is not only a great achievement but also the starting point towards both further market expansion and new innovation challenges, as always within the DNA of our company”.

During the last months, devoted to complete the recertification process, the company has been heavily devoted to continuous technical and scientific improvements: “Even if we have been confronted with certification renewal, we didn’t neglect clinical studies: we, indeed, kept investigating different clinical indications of use for SmartBone[®], achieving excellent results, as confirmed by the increasing trend of scientific publications ...” comments Giuseppe Perale, VP for Quality and Clinical Affairs “... which, overall, further substantiate complete safety and high performances of our product”.

IBI SA in a sentence

IBI SA is a Swiss innovative biomedical company, focused on research, development and production of medical devices for tissue engineering and regenerative medicine.

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