Biomatlante
Biologics Solutions

Press Release

BIOMATLANTE: A new step towards the MDR

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Nantes, France – Quality and Regulatory

Just after BSI last January, TÜV Süd Product Service GmbH is now the second Notified Body designated to issue CE Marking certifications under the European Medical Devices Regulation (MDR).

The Medical Device Regulation came into force on May 25th, 2017. It was implemented by the European Parliament to improve the EU approval system for medical devices.

"We are aware that the number of Notified Bodies able to deliver such services will be limited in future and therefore very satisfied to have selected TÜV Süd as our certification body", states Julien Dert, Biomatlante's CEO.

Biomatlante's complete portfolio is approved by TÜV Süd: MBCP® Synthetic Bone Substitutes, In'Oss Injectable Bone Substitute, EZ Cure Resorbable Collagen Membrane, Osteotwin Interference Screw.

The company is confident and focused on meeting the requirements of the MDR during the transition period, until May 26th, 2020 and TÜV Süd audits are already planned.

The MDR highlights post-market surveillance (PMS) and post-market clinical follow-up (PMCF) in compliance with the clinical evaluation MEDDEV 2.7/1, which the company chose to anticipate by having a clinical audit performed.

"Audit results were very positive and confirmed our strategy of compliance, reinforced by several clinical studies recently launched," points out Julien Dert.

With these new objectives in mind, Biomatlante is also pleased to announce the appointment of an additional Regulatory Affairs Specialist to strengthen the Regulatory Affairs & Quality Assurance team.

About BIOMATLANTE, experts in bone regeneration

Based near Nantes, Western France, Biomatlante is a world leader in synthetic bone regenerative technologies, providing innovative products for orthopedic, traumatological, spine and dental applications. Biomatlante markets its innovative products in more than 50 countries worldwide. Biomatlante prides itself on staying abreast of an ever-evolving market, thus ensuring its products meet the demanding requirements of surgeons and healthcare companies around the globe. Thanks to a robust research and development department, Biomatlante has been granted various patents and licenses covering both biomaterials and new associated technologies, based on its MBCP® Proprietary Technology.

Contact

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