BIOXIS
PHARMACEUTICALS

BIOXIS Pharmaceuticals granted ISO 13485 certification for Medical Devices

Lyon, France – May 2016: BIOXIS has been granted ISO 13485:2003 & EN ISO 13485: 2012 certification for the design, development, and manufacture of sterile dermal filler by the BSI. This certification confirms that BIOXIS has the highest level quality management throughout the life cycle of its medical device; ensuring the distribution of truly safe and effective products.
Founder and CEO Frédéric Bertaina stated "BIOXIS's certification to ISO 13485 standard demonstrates that our medical devices are manufactured with the highest level of traceability and quality control."

About BSI

BSI (British Standards Institution) is the world's first National Standards Body, and is responsible for originating many of the world's most commonly used management systems standards. BSI publishes over 2,700 standards annually. In Europe, BSI is a Notified Body, and conducts conformity assessment under the relevant EU Directives. The conformity assessment usually includes an audit of the manufacturer's quality system and - depending upon the unique classification of the device - review of relevant technical documentation provided by the manufacturer in support of the safety and performance claims for the device.
For more information, visit www.bsigroup.com

About BIOXIS Pharmaceuticals

Bioxis specializes in the discovery, development, production, and commercialization of innovative regenerative medicine products. Through groundbreaking solutions, the company develops popular products that help doctors improve quality of care.
For more information, visit www.bioxis.com

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