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OriGen Biomedical Receives European CE Certification for St. Elmo Manufacturing Site

The CE certification ensures comprehensive adherence to EU standards and the ability for increased capacity to continue to meet the growing needs of OriGen customers.

AUSTIN, JULY 2021: OriGen Biomedical, Inc., a leading producer of cryopreservation, cell culture, and respiratory products, is pleased to announce that we have received European CE certification for our St. Elmo Manufacturing Site, located at 2301 East St. Elmo Rd, Bldg One, Suite 110, Austin, TX 78744, USA.

The St. Elmo facility is operated under the same Quality Management System and managed by the same executive leadership team as the Burleson facility. This includes manufacturing using the same production procedures, quality procedures, and cGMP guidelines as those used at the Burleson facility. All processes, equipment, and product specifications were duplicated at the St. Elmo facility, resulting in no changes to the design or manufacturing process of the OriGen products produced at St. Elmo.

The St. Elmo facility has been successfully audited by OriGen Biomedical's Notified Body, GMED, and the St. Elmo facility is now included on the CE Certificate.

All CE-marked products manufactured at the St. Elmo facility will have the CE mark included on the product label and will be distributed within regions which accept FDA cleared, MDSAP certified, and CE marked products. For traceability, the Lot number for all products manufactured at the St. Elmo facility will have the prefix SE (for St. Elmo).

OriGen initiated expansion into the St. Elmo facility to increase capacity to continue to meet the needs of our customers in the hospital, laboratory, cell therapy, and gene therapy industries. Quality is the foundation of OriGen products and this regulatory achievement represents OriGen's commitment to maintaining the highest quality standards within the competitive and closely regulated industry of medical device manufacturing.

Please see more information regarding OriGen certificates on our Regulatory Page.

The CE Mark is mandatory for specific product groups in the European Economic Area (EEA) which consists of the 27 Member States of the EU and the European Free Trade Association (EFTA) countries of Iceland, Norway, Switzerland, and Liechtenstein. The CE mark indicates that the product may be sold freely in any part of the EEA, regardless of its country of origin.

More information about CE certification can be obtained here.

If you have any questions regarding the new St. Elmo facility, please contact us. Thank you for your continued partnership.

ABOUT ORIGEN BIOMEDICAL

OriGen Biomedical, Inc. is a leading producer of cryopreservation, cell culture, and intensive respiratory care products. OriGen's focus is to produce a range of products to support the treatment of cancer, genetic conditions, and other life-threatening diseases. Our products are designed with the patient and user in mind and we strive to maintain excellent customer service to ensure that patient care is the priority. Quality is the foundation of all product designs at OriGen, and each product is produced with the intention that it will improve patient health. Founded in 1997 and headquartered in Austin, Texas, OriGen is certified annually to ISO 13485 standards and regularly inspected by the FDA, MDSAP, ISO certification organizations, and our customers. To learn more visit www.origen.com and follow us on LinkedIn and Twitter.

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