U.S. FOOD & DRUG ADMINISTRATION
CENTER FOR BIOLOGICS EVALUATION AND RESEARCH

U.S. Food & Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
www.fda.gov

Certificate No. CT:66JT-7DPR

Application Number: 1364-19

CERTIFICATE TO FOREIGN GOVERNMENT

In order to allow the importation of United States products into foreign countries, the U.S. Food and Drug Administration (FDA) certifies the following information concerning the product(s) to be exported listed below:

BioStem Life Sciences, located at 2836 Center Port Circle, Pompano Beach, FL 33064, USA, manufactured the following Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps):

Catalog ID	Product Name
200-001	Vendaje Amnion Membrane
200-004	Vendaje Amnion Membrane
200-008	Vendaje Amnion Membrane
200-016	Vendaje Amnion Membrane
200-024	Vendaje Amnion Membrane
200-032	Vendaje Amnion Membrane
300-001	Vendaje dual layer
300-004	Vendaje dual layer
300-008	Vendaje dual layer
300-016	Vendaje dual layer
300-024	Vendaje dual layer
300-032	Vendaje dual layer
300-036	Vendaje dual layer
500-050	Vendaje optic
500--079	Vendaje optic
500-113	Vendaje optic

The product(s) described above and the establishment(s) where it is produced are subject to FDA jurisdiction and regulated solely under section 361 of the Public Health Service Act (PHS Act) and regulations promulgated thereunder. and regulations promulgated thereunder. The company listed above has certified to the FDA that the HCT/P meets the requirements of FDA regulation, Title 21, Code of Federal Regulations Part 1271, Human Cells, Tissues, and Cellular and Tissue-Based Products.

It is certified that the above listed HCT/P may be marketed in, and legally exported from, the United States of America at this time. The company listed above is subjected to periodic inspections. The last inspection showed that the plant(s) at that time, appeared to be in compliance with the requirements of FDA regulation, Title 21, Code of Federal Regulations Part 1271.

Signature_____

Robert A. Sausville
Director
Division of Case Management
Office of Compliance and Biologics Quality
Center for Biologics Evaluation and Research
Food and Drug Administration

This certificate is valid from July 31, 2019 to July 30, 2021.