



Comunicación EMC-CE-GG-01-046

Quito, 09 de Noviembre de 2022

Para: Dra. Lorena Peñaherrera
Coordinadora Zonal Nro. 1, INDOT

Asunto: Actualización y Apostilla de Certificado de libre Venta de Lifelink

Estimada Dra. Lorena Peñaherrera, reciba un Cordial Saludo!

Me dirijo a usted en la oportunidad de hacer entrega de la documentación correspondiente:

- Certificado de Gobierno Extranjero o Libre Venta a Ecuador emitido por la FDA, con vigencia desde el 22 de Agosto del 2022, hasta 21 de Agosto 2024.

De igual forma los mismos fueron remitidos electrónicamente a los correos institucionales coordinacion.zonal1@indot.gob.ec, lorenepenaherrera@indot.gob.ec

Con la entrega de estos documentos esperamos poder dar continuidad a nuestra labor como Servicio de Apoyo y cumplir con la importación de los tejidos solicitados para la atención de la salud de los ciudadanos ecuatorianos.

Con especial consideración, queda de ustedes.

Atentamente,



Firmado electrónicamente por:
SHEYLA DEL
VALLE LOPEZ
TRAZABAL

Sheyla Lopez
Representante Legal

EMC-CE-GG-01



APOSTILLE

(Convention de La Haye du 5 octobre 1961)

1. Country: *United States of America*

This public document

2. has been signed by *Robert A. Sausville*

3. acting in the capacity of *Director, Office of Compliance and Biologics Quality*

4. bears the seal/stamp of *U.S. Department of Health and Human Services*

Certified

5. at Washington, D.C.

6. the *twenty-ninth of October, 2022*

7. by *Assistant Authentication Officer, United States Department of State*

8. No. *22060139-6*

9. Seal/Stamp:

10. Signature:

Patrick O. Hatchett



**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:C6KS-TEUX

Application Number: 1555-22

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:

LifeLink Tissue Bank, located at 9661 Delaney Creek Blvd, Tampa, FL 33619, USA, manufactured the following Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps):

Product Name

Bone, Tendon, Meniscus, Ligament, Cartilage, Fascia

Country Destination: ECUADOR

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. 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 August 22, 2022 to August 21, 2024.

