

Porcine Pericardial Tissue, Bovine Pericardial Tissue and Bovine Jugular Vein or Cross-linked Collagen Matrix for Biomedical Use

This document is for the export to Mexico of bovine pericardial or jugular vein or cross-linked collagen matrix derived from these tissues and porcine pericardial tissue, of U.S. origin or imported origin, intended for use in the biomedical industry.

In the event that the country of origin for the raw material is not the United States, the origin health certificate must be referenced appropriately on the U.S. Export Certificate for Animal Products and must provide the additional required statements as outlined below.

Options which are not applicable for the product being exported should not be included in the certificate.

The bilingual certification statements should be provided in the Additional Declarations section of the certificate Export Certificate for Animal Products (VS Form 16-4) and continuation page VS form 16-4A as needed. A notarized affidavit from the manufacturer is required to support these statements on the export certificate issued by APHIS Veterinary Services.

This office has on file a notarized affidavit from [company name] verifying the accuracy of the following statements: / *Esta oficina cuenta en su expediente con una declaración notariada de [nombre de la compañía] que verifica la exactitud de las siguientes declaraciones:*

[Select appropriate certification statement 1 depending on the species of origin]

1. The raw bovine material originates in the United States or was legally imported from _____ (indicate the country), a country categorized by the World Animal Health Organization as Negligible Risk for BSE (bovine spongiform encephalopathy). / *La materia prima de origen bovino es originaria de Estados Unidos o fue legalmente importado de _____ (indicar el país), país considerado por la Organización Mundial de Sanidad Animal (OIE) como de riesgo insignificante para la encefalopatía espongiforme bovina (EEB).*

1. The raw porcine material originates in the United States, or was legally imported from _____ (indicate the country). / *La materia prima de origen porcino procede de los Estados Unidos o fue legalmente importado de _____ (indicar el país).*

(Note: Other than the United States, Australia and Denmark are the only countries of origin contemplated at this time.) (*Nota: Aparte de los Estados Unidos, Australia y Dinamarca son los únicos países considerados hasta este momento.*)

[Select appropriate certification statement 2]

(Choose the correct species of origin option and indicate the concentration of buffered isotonic glutaraldehyde solution or physiological saline used.)

2. The [bovine] [porcine] product was preserved in a buffered isotonic glutaraldehyde solution at _____ (indicate concentration) and packed in jars for transport. / *El producto [bovino] [porcino] fue conservado en solución amortiguada isotónica de glutaraldehído al _____ (indicar concentración) dentro de un frasco para su transportación.*

(Note: Bovine jugular vein should be packed in 0.2- 0.5% buffered isotonic glutaraldehyde solution. Bovine pericardial tissue should be packed in 0.5% buffered isotonic glutaraldehyde solution. Porcine pericardial tissue should be packed in 0.20% - 0.25% isotonic buffered glutaraldehyde solution. / *La vena yugular bovina debe ser empacada en solución amortiguada de glutaraldehído isotónico 0.2-0.5%. El tejido pericárdico bovino debe empaketarse en solución amortiguada de glutaraldehído isotónico al 0,5%. El tejido pericárdico porcino se debe empaketar en solución amortiguada de glutaraldehído isotónica al 0,20% al 0,25%.*)

2. For its transportation, the bovine/porcine pericardial product is conserved in a solution of physiological saline. / *El producto pericardio de origen bovino/porcino se encuentra conservado en solución salina fisiológica para su transportación.*

(Certify the following for imported raw material. The original health certificate issued by the exporting country must accompany the shipment.)

3. The consignment described below was legally imported into the United States from _____ (country) accompanied by the attached certificate(s), number(s) _____. / *El embarque descrito abajo fue legalmente importado dentro de los Estados Unidos de (indicar el país), acompañado del certificado zoonosanitario (indicar número).*
[Note: Australia and Denmark are the only countries currently permitted. / *Australia y Dinamarca on los úncios países permitidos actualmente).*]

(Certify the following for United States origin and imported material. The original health certificate issued by the exporting country must provide this statement in the event that the raw material was imported.)

4. The animals from which the raw material was derived were subjected to ante-mortem and post-mortem inspection and were slaughtered in an establishment under official control. / *Los animales de donde procede la materia prima fueron sujetos a inspección ante y post-mortem y fueron sacrificados en un establecimiento bajo control oficial.*

(Certify the following for United States origin material. The origin health certificate issued by the exporting country must provide this statement in the event that the raw material was imported.)

5. The animals from which the raw material was derived were not sacrificed as part of a program for the eradication of any disease agent transmissible through the product. / *Los animales de donde procede la materia prima no fueron sacrificados como parte de un programa para la erradicación de cualquier agente de enfermedad transmisible a través del producto.*